



Billing Code 3410-02-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 990

[Doc. No. AMS-SC-19-0042; SC19-990-2 IR]

Establishment of a Domestic Hemp Production Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule establishes a new part specifying the rules and regulations to produce hemp. This action is mandated by the Agriculture Improvement Act of 2018, which amended the Agricultural Marketing Act of 1946. This rule outlines provisions for the Department of Agriculture (USDA) to approve plans submitted by States and Indian Tribes for the domestic production of hemp. It also establishes a Federal plan for producers in States or territories of Indian Tribes that do not have their own USDA-approved plan. The program includes provisions for maintaining information on the land where hemp is produced, testing the levels of delta-9 tetrahydrocannabinol, disposing of plants not meeting necessary requirements, licensing requirements, and ensuring compliance with the requirements of the new part.

DATES: *Effective date:* This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] through [INSERT DATE 730 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Comment due dates: Comments received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered prior to issuance of a final rule. Pursuant to the Paperwork Reduction Act (PRA), comments on the information collection burden must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons are invited to submit written comments concerning this rule and the proposed information collection. Comments should be submitted via the Federal eRulemaking portal at www.regulations.gov. Comments may also be filed with Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; or Fax: (202) 720-8938. All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours or can be viewed at: www.regulations.gov. All comments submitted in response to this rule will be included in the record and will be made available to the public.

FOR FURTHER INFORMATION CONTACT: Bill Richmond, Chief, U.S. Domestic Hemp Production Program, Specialty Crops Program, AMS, USDA; 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202)720-8938, or E-mail: William.Richmond@usda.gov or Patty Bennett, Director, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA at the same address and phone number above or E-mail: Patty.Bennett@usda.gov.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202)720-8938, or E-mail: Richard.Lower@usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Section 10113 of Public Law 115-334, the Agriculture Improvement Act of 2018 (2018 Farm Bill). Section 10113 amended the Agricultural Marketing Act of 1946 (AMA) by adding Subtitle G (sections 297A through 297D of the AMA). Section 297B of the AMA requires the Secretary of Agriculture (Secretary) to evaluate and approve or disapprove State or Tribal plans regulating the production of hemp. Section 297C of the AMA requires the Secretary to establish a Federal plan for producers in States and territories of Indian Tribes not covered by plans approved under section 297B. Lastly, section 297D of the AMA requires the Secretary to promulgate regulations and guidelines relating to the production of hemp, including sections 297B and 297C, in consultation with the U.S. Attorney General. USDA is committed to issuing the final rule expeditiously after reviewing public comments and obtaining additional information during the initial implementation. This interim final rule will be effective for two years and then be replaced with a final rule.

I. Introduction.

Hemp is a commodity that can be used for numerous industrial and horticultural purposes including fabric, paper, construction materials, food products, cosmetics, production of

cannabinoids (such as cannabidiol or CBD), and other products.¹ While hemp was produced previously in the U.S. for hundreds of years, its usage diminished in favor of alternatives. Hemp fiber, for instance, which had been used to make rope and clothing, was replaced by less expensive jute and abaca imported from Asia. Ropes made from these materials were lighter and more buoyant, and more resistant to salt water than hemp rope, which required tarring. Improvements in technology further contributed to the decline in hemp usage. The cotton gin, for example, eased the harvesting of cotton, which replaced hemp in the manufacture of textiles.

Hemp production in the U.S. has seen a resurgence in the last five years; however, it remains unclear whether consumer demand will meet the supply. High prices for hemp, driven primarily by demand for use in producing CBD, relative to other crops, have driven increases in planting. Producer interest in hemp production is largely driven by the potential for high returns from sales of hemp flowers to be processed into CBD oil.

USDA regulates the importation of all seeds for planting to ensure safe agricultural trade. Hemp seeds can be imported into the United States from Canada if accompanied by either: 1) a phytosanitary certification from Canada's national plant protection organization to verify the origin of the seed and confirm that no plant pests are detected; or 2) a Federal Seed Analysis Certificate (SAC, PPQ Form 925) for hemp seeds grown in Canada. Hemp seeds imported into

¹ The 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act). See section 297D(c)(1) ("Nothing in this subchapter shall affect or modify . . . the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); section 351 of the Public Health Service Act (42 U.S.C. 262); or the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services. . . ." under those Acts). Accordingly, products containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as FDA-regulated products containing any other substance.

the United States from countries other than Canada may be accompanied by a phytosanitary certificate from the exporting country's national plant protection organization to verify the origin of the seed and confirm that no plant pests are detected. Accordingly, since importation of seed is covered under USDA Animal and Plant Health Inspection Service (APHIS) regulations, this rule does not further address hemp seed imports or exports. For imports of hemp plant material, APHIS will have jurisdiction for any pest related issues if they arise.

The 2018 Farm Bill allows for the interstate transportation and shipment of hemp in the United States. This rule does not affect the exportation of hemp. Should there be sufficient interest in exporting hemp in the future, USDA will work with industry and other Federal agencies to help facilitate this process.

Prior to the 2018 Farm Bill, *Cannabis sativa* L. with delta-9 tetrahydrocannabinol (THC) levels greater than 0.3% fell within the definition of "marihuana" under the Controlled Substances Act (CSA), 21 U.S.C. 801 et seq., and was therefore a Schedule I controlled substance unless it fell under a narrow range of exceptions (e.g., the "mature stalks" of the plant).² As a result, many aspects of domestic production of what is now defined as hemp was limited to persons registered under the CSA to do so. Under the Agricultural Act of 2014 (2014 Farm Bill), Pub. L. 113-79, State departments of agriculture and institutions of higher education were permitted to produce hemp as part of a pilot program for research purposes. The authority

² Although the statutory spelling is "marihuana" in the Controlled Substances Act, this rule uses the more commonly used spelling of marijuana.

for hemp production provided in the 2014 Farm Bill was extended by the 2018 Farm Bill, which was signed into law on December 20, 2018.

The 2018 Farm Bill requires USDA to promulgate regulations and guidelines to establish and administer a program for the production of hemp in the United States. Under this new authority, a State or Indian Tribe that wants to have primary regulatory authority over the production of hemp in that State or territory of that Indian Tribe may submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. For States or Indian Tribes that do not have approved plans, the Secretary is directed to establish a Departmental plan to monitor and regulate hemp production in those areas.

There are similar requirements that all hemp producers must meet. These include: licensing requirements; maintaining information on the land on which hemp is produced; procedures for testing the THC concentration levels for hemp; procedures for disposing of non-compliant plants; compliance provisions; and procedures for handling violations.

After extensive consultation with the Attorney General, USDA is issuing this interim final rule to establish the domestic hemp production program and to facilitate the production of hemp, as set forth in the 2018 Farm Bill. This interim rule will help expand production and sales of domestic hemp, benefiting both U.S. producers and consumers. With the publication of the interim rule, USDA will begin to implement the hemp program including reviewing State and Tribal plans and issuing licenses under the USDA hemp plan. There is also a 60-day comment period during which interested persons may submit comments on this interim rule. The comment period will close on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. After reviewing and evaluating the comments, USDA will

draft and publish a final rule within two years of the date of publication. USDA will evaluate all information collected during this period to adjust, if necessary, this rule before finalizing.

For the purposes of this new part, and as defined in the 2018 Farm Bill, the term “hemp” means the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Delta-9 tetrahydrocannabinol, or THC, is the primary intoxicating component of cannabis. Cannabis with a THC level exceeding 0.3 percent is considered marijuana, which remains classified as a schedule I controlled substance regulated by the Drug Enforcement Administration (DEA) under the CSA.

The term “State” means any of one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States. The term “Indian Tribe” or “Tribe” is the same definition as in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304). The interim rule also includes the definition of “territory of an Indian Tribe” to provide clarity to the term because the Act does not define it. The definition adopts the definition “Indian Country” in 18 U.S.C. 1151 because it is a commonly acceptable approach to determine a tribal government’s jurisdiction. Under an approved Tribal plan, the Indian Tribe will have regulatory authority over Indian Country under its jurisdiction.³ A full list of terms and definitions relating to this part can

³ We note that if an Alaskan Native Corporation wants to produce hemp on land it owns in fee simple, it would need to have a State or USDA license, whichever is applicable, because that land does not qualify as Indian Country and it does not have jurisdiction over that land.

be found under “Definitions” in section IV.

II. State and Tribal Plans.

If a State or Indian Tribes wants to have primary regulatory authority over the production of hemp in that State or territory of that Indian Tribe they may submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. State or Tribal plans must be submitted to USDA and approved prior to their implementation. Nothing preempts or limits any law of a State or Tribe that regulates the production of hemp and is more stringent than the provisions in the 2018 Farm Bill. State and Tribal plans developed to regulate the production of hemp must include certain requirements when submitted for USDA approval. These requirements are outlined in the following sections.

A. Land used for production.

Plans will need to contain a process by which relevant information regarding the land used for hemp production in their jurisdiction is collected and maintained. All information on hemp production sites must be collected for each producer covered by the State or Tribal plan. The information required to be collected includes a legal description of the land and geospatial location, which the USDA Farm Service Agency (FSA) can help provide, for each field, greenhouse, or other site where hemp is produced. Geospatial location is required because many rural locations do not have specific addresses and these coordinates will assist with the proper identification of hemp production locations. Per statute, States and Tribes will need to retain these records for three years.

In addition to the land information required to be submitted to the appropriate State or Tribe, licensed producers must also report their hemp crop acreage to the FSA. When reporting

to FSA, producers must provide their State or Tribe-issued license or authorization number. The requirement that producers report hemp crop acreage to FSA establishes an identification system for hemp production nationwide and complies with the information sharing requirements of the 2018 Farm Bill. A link to FSA information on how to report hemp crop acreage to FSA is available at

<https://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdfiles/FactSheets/2019/crop-acreage-reporting-19.pdf> and will be provided on the USDA hemp production program website. USDA believes that most producers who will plant hemp already report land use data to FSA for other crops and to apply for various FSA programs, including those for hemp. FSA offices are located in various counties within each State and are designed to be a single location where customers can access services from USDA agencies including FSA, AMS, Natural Resources Conservation Service (NRCS) and Rural Development (RD). These offices currently serve the agricultural industry within their communities and provide producers access to an office for establishing farm and producer records, a place for producers to record their licensing information, and a place to report crop acreage. The producer may, with supporting documentation, also update its FSA farm records for leases, sub-leases, or ownership of land.

Under the hemp pilot program authorized under the terms of the 2014 Farm Bill, various States developed seed certification programs to help producers identify hemp seed that would work well in their specific geographical areas. USDA will not include a seed certification program in this rule because the same seeds grown in different geographical locations and growing conditions can react differently. For example, the same seed used in one State to produce hemp plants with THC concentrations less than 0.3%, can produce hemp plants with

THC concentrations of more than 0.3% when planted in a different State. We have also found that the technology necessary to determine seed planting results in different locations is not advanced enough at this time to make a seed-certification scheme feasible. Additionally, we do not have accurate data at this time on the origin of most hemp seed planted in the U.S.

B. Sampling and testing for delta-9 tetrahydrocannabinol.

State and Tribal plans must incorporate procedures for sampling and testing hemp to ensure the cannabis grown and harvested does not exceed the acceptable hemp THC level. Sampling procedures, among other requirements, must ensure that a representative sample of the hemp production is physically collected and delivered to a DEA-registered laboratory for testing. Within 15 days prior to the anticipated harvest of cannabis plants, a Federal, State, local, or Tribal law enforcement agency or other Federal, State or Tribal designated person shall collect samples from the flower material from such cannabis plants for delta-9 tetrahydrocannabinol concentration level testing. If producers delay harvest beyond 15 days, the plant will likely have a higher THC level at harvest than the sample that is being tested. This requirement will yield the truest measurement of the THC level at the point of harvest. Accepting that a pre-harvest inspection is best to identify suspicious plants and activities, and that the sample should be taken as close to harvest as possible, the time was selected based on what would be a reasonable time for a farmer to harvest an entire field. This 15-day post-sample harvest window was also designed to allow for variables such as rain and equipment delays. We are requesting comments and information regarding the 15-day sampling and harvest timeline.

Testing procedures must ensure the testing is completed by a DEA-registered laboratory using a reliable methodology for testing the THC level. The THC concentration of all hemp

must meet the acceptable hemp THC level. Samples must be tested using post-decarboxylation or other similarly reliable analytical methods where the total THC concentration level reported accounts for the conversion of delta-9-tetrahydrocannabinolic acid (THCA) into THC. Testing methodologies currently meeting these requirements include those using gas or liquid chromatography with detection. The total THC, derived from the sum of the THC and THCA content, shall be determined and reported on a dry weight basis. In order to provide flexibility to States and Tribes in administering their own hemp production programs, alternative sampling and testing protocols will be considered if they are comparable and similarly reliable to the baseline mandated by section 297B(a)(2)(ii) of the AMA and established under the USDA plan and procedures. USDA procedures for sampling and testing will be issued concurrently with this rule and will be provided on the USDA website.

Sections 297B(a)(2)(A)(iii) and 297C(a)(2)(C) require that cannabis plants that have a THC concentration level of greater than 0.3% on a dry weight basis be disposed of in accordance with the applicable State, Tribal, or USDA plan. Because of this requirement, producers whose cannabis crop is not hemp will likely lose most of the economic value of their investment. Thus, USDA believes that there must be a high degree of certainty that the THC concentration level is accurately measured and is in fact above 0.3% on a dry weight basis before requiring disposal of the crop.

The National Institute of Standards and Technology (NIST) Reference on Constants, Units, and Uncertainty states that “measurement result is complete only when accompanied by a quantitative statement of its uncertainty. The uncertainty is required in order to decide if the result is adequate for its intended purpose and to ascertain if it is consistent with other similar

results.”⁴ Simply stated, knowing the measurement of uncertainty is necessary to evaluate the accuracy of test results.

This interim rule requires that laboratories calculate and include the measurement of uncertainty (MU) when they report THC test results. Hemp producers must utilize laboratories that use appropriate, validated methods and procedures for all testing activities and who also evaluate measurement of uncertainty. Laboratories should meet the AOAC International⁵ standard method performance requirements for selecting an appropriate method.

This interim rule defines “measurement of uncertainty” as “the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.” This definition is based on the definition of “uncertainty (of measurement)” in section 2.2.3 of the Joint Committee for Guides in Metrology⁶ 100:800, Evaluation of measurement data — Guide to the expression of uncertainty in measurement (JCGM Guide). NIST Technical Note 1297, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results (TN 1297), is based on the JCGM Guide. USDA also relied on the Eurachem/Co-Operation on International Traceability in Analytical Chemistry’s “Guide on Use of Uncertainty Information in Compliance

⁴ <https://physics.nist.gov/cuu/Uncertainty/international1.html>

⁵ USDA established the Association of Official Agricultural Chemists in 1884. In 1965, it changed its name to the Association of Official Analytical Chemists and became an independent organization in 1979. In 1991, it adopted its current, legal name as AOAC International.

⁶ The Joint Committee for Guides in Metrology is composed of international organizations working in the field of metrology. Its membership includes the Bureau International des Poids et Mesures, the Organisation Internationale de Métrologie Légale, the International Organization for Standardization, the International Electrotechnical Commission, the International Union of Pure and Applied Chemistry, the International Union of Pure and Applied Physics, the International Federation of Clinical Chemistry and Laboratory Medicine, and the International Laboratory Accreditation Cooperation.

Assessment, First Edition 2007”. Colloquially, the measurement of uncertainty is similar to a margin of error. When the measurement of uncertainty, normally expressed as a +/- with a number, (e.g. +/- 0.05) is combined with the reported measurement, it produces a range and the actual measurement has a known probability of falling within that range (typically 95%).

This interim rule requires that laboratories report the measurement of uncertainty as part of any hemp test results. The rule also includes a definition of “acceptable hemp THC level” to account for the uncertainty in the test results. The reported THC concentration level of a sample may not be the actual concentration level in the sample. The actual THC concentration level is within the distribution or range when the reported THC concentration level is combined with the measurement of uncertainty.

It bears emphasis that this rule does not alter Federal law with regard to the definition of hemp or marihuana. As stated above, the 2018 Farm Bill defines hemp as the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 THC of not more than 0.3 percent on a dry weight basis. Likewise, the Federal (CSA) definition of marihuana continues to include those parts of the cannabis plant as specified in 21 U.S.C. 802(16) (and derivatives thereof) that contain more than 0.3 percent delta-9 THC on a dry weight basis. The foregoing provisions of Federal law remain in effect for purposes of Federal criminal prosecutions as well as Federal civil and administrative proceedings arising under the CSA. However, for purposes of this rule (i.e., for purposes of determining the obligations of licensed hemp growers under the applicable provisions of the 2018 Farm Bill), the term “acceptable hemp THC level” is used to account for the uncertainty in the test results.

The definition of “acceptable hemp THC level” explains how to interpret test results with the measurement of uncertainty with an example. The application of the measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution, or range. If 0.3% or less is within the distribution or range, then the sample will be considered to be hemp for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans. For example, if a laboratory reports a result as 0.35% with a measurement of uncertainty of +/- 0.06, the distribution or range is 0.29% to 0.41%. Because 0.3% is within that distribution or range, the sample, and the lot it represents, is considered hemp for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans. However, if the measurement of uncertainty for that sample was 0.02%, the distribution or range is 0.33% to 0.37%. Because 0.3% or less is not within that distribution or range, the sample is not considered hemp for the purpose of plan compliance, and the lot it represents will be subject to disposal. Thus the “acceptable hemp THC level” is the application of the measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis producing a distribution or range that includes 0.3% or less. As such, the regulatory definition of “acceptable hemp THC level” describes how State, Tribal, and USDA plans must account for uncertainty in test results in their treatment of cannabis. Again, this definition affects neither the statutory definition of hemp, 7 U.S.C. 1639o(1), in the 2018 Farm Bill nor the definition of “marihuana,” 21 U.S.C. 802(16), in the CSA.

The laboratories conducting hemp testing must be registered by the DEA to conduct chemical analysis of controlled substances (in accordance with 21 CFR 1301.13). Registration is

necessary because laboratories could potentially handle cannabis that tests above the 0.3% concentration of THC on a dry weight basis, which is, by definition, marijuana and a Schedule 1 controlled substance. Instructions for laboratories to obtain DEA registration, along with a list of approved laboratories, will be posted on the USDA Domestic Hemp Production Program website.

USDA is considering establishing a fee-for-service hemp laboratory approval process for labs that wish to offer THC testing services. USDA approved laboratories would be approved by the USDA, AMS, Laboratory Approval Service, which administers the Laboratory Approval Program (LAP). USDA-approved laboratories would need to comply with the LAP requirements, as established under “Laboratory Approval Program - General Policies & Procedures” (www.ams.usda.gov/services/lab-testing/lab-approval), which describes the general policies and procedures for a laboratory to apply for and maintain status in a LAP. Under the LAP, an individual program for hemp would be developed, with a set of documented requirements to capture specific regulatory, legal, quality assurance and quality control, and analytical testing elements. A requirement for a testing laboratory to be approved by USDA would be in addition to the requirement in the final rule that the laboratory be registered with DEA.

In addition to requiring ISO 17025 accreditation, which assesses general competence of testing laboratories, the LAP would provide a way for USDA to accredit that laboratories perform to a standard level of quality. When DEA registers a lab to handle narcotics, they do not require the lab to be accredited. This is an important factor, as the issue of providing assurance as to proper testing was raised on numerous occasions during the USDA outreach process that

was conducted prior to developing this rule. The LAP would give USDA the proper oversight of the laboratories doing the testing, providing quality assurance and control procedures that ensure a validated and qualified analysis, and defensible data. Should USDA establish a lab approval process, a list of USDA approved laboratories that are also registered with the DEA would be posted on the USDA Domestic Hemp Production Program website. Although this proposal is not reflected in the regulatory text of this interim final rule, USDA is seeking comment on it to determine whether to incorporate it in the subsequent final rule.

Alternatively, USDA is considering requiring all laboratories testing hemp to have ISO 17025 accreditation. We are requesting comment on this requirement as well and are interested to learn about the number of labs that already have this accreditation, the associated burden, and the potential benefits of such a requirement.

C. Disposal of non-compliant plants.

State and Tribal plans are also required to include procedures for ensuring effective disposal of plants produced in violation of this part. If a producer has produced cannabis exceeding the acceptable hemp THC level, the material must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a schedule I controlled substance under the CSA. Consequently, the material must be collected for destruction by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, or local law enforcement officer.

D. Compliance with Enforcement Procedures Including Annual Inspection of Hemp Producers

State and Tribal plans must include compliance procedures to ensure hemp is being produced in accordance with the requirements of this part. This includes requirements to

conduct annual inspections of, at a minimum, a random sample of hemp producers to verify hemp is not being produced in violation of this part. These plans also must include a procedure for handling violations. In accordance with the 2018 Farm Bill, States and Tribes with their own hemp production plans have certain flexibilities in determining whether hemp producers have violated their approved plans. However, there are certain compliance requirements that all State and Tribal plans must contain. This includes procedures to identify and attempt to correct certain negligent acts, such as failing to provide a legal description of the land on which the hemp is produced, not obtaining a license or other required authorizations from the State or tribal government or producing plants exceeding the acceptable hemp THC level. States and Tribes may require additional information in their plans. In the context of this part, negligence is defined as a failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part. This definition employed in this rule is derived from the definition of negligence in Black's Law Dictionary. *See* BLACK'S LAW DICTIONARY (10th ed. 2014) (defining *negligence* as “[t]he failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation”).

This rule specifies that hemp producers do not commit a negligent violation if they produce plants that exceed the acceptable hemp THC level and use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5 percent on a dry weight basis. USDA recognizes that hemp producers may take the necessary steps and precautions to produce hemp, such as using certified seed, using other seed that has reliably grown compliant plants in other parts of the country, or engaging in other best practices, yet still produce plants that exceed the acceptable hemp THC level. USDA seeks comments whether there are other

reasonable efforts to be considered. We believe that a hemp producer in that scenario has exercised a level of care that a reasonably prudent person would exercise if the plant does not have a THC concentration of more than 0.5 percent on a dry weight basis. USDA arrived at that percentage by examining the test results of samples taken from several States that have a hemp research program under the 2014 Farm Bill and by reviewing results from plants grown from certified seed as well as uncertified seed and tested using different testing protocols. Under this scenario, although a producer would not be considered “negligent,” they would still need to dispose of the plants if the THC concentration exceeded the acceptable hemp THC level.

In developing the compliance requirements of State and Tribal plans, USDA recognizes that there may be significant differences across States and Tribes in how they will administer their respective hemp programs. Accordingly, as long as, at a minimum, the requirements of the 2018 Farm Bill are met, States and Tribes are free to determine whether or not a licensee under their applicable plan has taken reasonable steps to comply with plan requirements.

In cases where a State or Tribe determines a negligent violation has occurred, a corrective action plan shall be established. The corrective action plan must include a reasonable date by which the producer will correct the negligent violation. Producers operating under a corrective action plan must also periodically report to the State or Tribal government, as applicable, on their compliance with the plan for a period of not less than two calendar years following the violation. A producer who negligently violates a State or Tribal plan three times in a five-year period will be ineligible to produce hemp for a period of five years from the date of the third violation. Negligent violations are not subject to criminal enforcement action by local, Tribal, State, or Federal government authorities.

State and Tribal plans also must contain provisions relating to producer violations made with a culpable mental state greater than negligence, meaning, acts made intentionally, knowingly, or with recklessness. This definition is derived from the definition of negligence in Black's Law Dictionary. *See* BLACK'S LAW DICTIONARY (10th ed. 2014) (giving as a definition of *negligence* “[t]he failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation”). If it is determined a violation was committed with a culpable mental state greater than negligence, the State department of agriculture or tribal government, as applicable, shall immediately report the producer to the Attorney General, USDA, and the chief law enforcement officer of the State or Tribe.

State and Tribal plans also must prohibit any person convicted of a felony related to a controlled substance under State or Federal law before, on, or after the enactment of the 2018 Farm Bill from participating in the State or Tribal plan and from producing hemp for 10-years following the date of conviction. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

To meet this requirement, the State or Indian Tribe will need to review criminal history reports for each applicant. When an applicant is a business entity, the State or Indian Tribe must review the criminal history report for each key participant in the business. The State and Tribe may determine the appropriate method for obtaining the criminal history report for their licensees in their plan. Finally, any person found by the USDA, State, or Tribal government to have materially falsified any information submitted to this program will be ineligible to participate.

E. Information sharing.

State and Tribal plans also must contain procedures for reporting specific information to USDA. This is separate from the requirement to report hemp crop acreage with FSA as discussed above. The information required here includes contact information for each hemp producer covered under the plan including name, address, telephone number, and email address (if available). If the producer is a business entity, the information must include the full name of the business, address of the principal business location, full name and title of the key participants, an email address if available, and EIN number of the business entity. Producers must report the legal description and geospatial location for each hemp production area, including each field, greenhouse, or other site, used by them, as stated in section A of this preamble. The report also shall include the status of the license or other required authorization from the State or Tribal government, as applicable, for each producer under a hemp production plan. States and Tribes will submit this information to USDA not later than 30 days after the date it is received using the appropriate reporting requirements as determined by USDA. These reporting requirements are found at § 990.70 in this rule. Further explanation of the specific information to be submitted, the appropriate format, and the specific due dates for the information is discussed below. This information submitted from each State and Tribal plan, along with the equivalent information collected from individuals participating under the USDA plan, will be assembled and maintained by USDA and made available in real time to Federal, State, and local law enforcement as required by the 2018 Farm Bill. All information supporting, verifying, or documenting the information submitted to USDA must be maintained by the States and Tribes for at least three years.

F. Certification of resources.

All State and Tribal plans submitted for USDA approval must also have a certification stating the State or Tribe has the resources and personnel necessary to carry out the practices and procedures described in their plan. Section 297B of the AMA requires this certification and the information is important to USDA's approval of State and Tribal plans in that all such plans must be supported by adequate resources to effectively administer them.

G. Plan approval, technical assistance and USDA oversight.

During the plan development process, States and Tribes are encouraged to contact USDA so we may provide technical assistance in developing plan specifics. USDA will not review, approve or disapprove plans until after the effective date of this interim rule. Once USDA formally receives a plan, USDA will have 60 days to review the submitted plan. USDA may approve plans which comply with the 2018 Farm Bill and with the provisions of this rule. If a plan does not comply with all requirements of the Act and this part it will be rejected. USDA will consult with the Attorney General throughout this process.

When plans are rejected, USDA will provide a letter of notification outlining the deficiencies identified. The State or tribal government may then submit an amended plan for review. If the State or Tribe disagrees with the determination made by USDA regarding the plan, a request for reconsideration can be submitted to USDA using the appeal process as outlined in section V. of this rule. Plans submitted by States and Tribes must be approved by USDA before they can be implemented.

USDA will use the information outlined here and as directed in the 2018 Farm Bill when evaluating State and Tribal plans for approval. States and Tribes can submit their plans to

USDA through electronic mail at farmbill.hemp@usda.gov or by postal carrier to USDA. The specific address is provided on the USDA Domestic Hemp Production Program website.

If the State or Tribal plan application is complete and meets the criteria of this part, USDA shall issue an approval letter. Approved State and Tribal plans, including their respective rules, regulations and procedures, shall be posted on USDA's hemp program website.

Once a plan has received approval from USDA, it will remain in effect unless revoked by USDA pursuant to the revocation procedures discussed below, or unless the State or Tribe makes substantive revisions to their plan or their laws that alter the way the plan meets the requirements of this regulation. Additionally, changes to the provisions or procedures under this rule or to the language in the 2018 Farm Bill may require plan revision and resubmission to USDA for approval. Should States or Tribes have questions regarding the need to resubmit their plans, they should contact USDA for guidance. Statutory amendments could result in revocation of some or all plans.

A State or tribal government may submit an amended plan to USDA for approval if: (1) the Secretary disapproves a State or Tribal plan; or (2) The State or Tribe makes substantive revisions to their plan or to their laws that alter the way the plan meets the requirements of this regulation, or as necessary to bring the plan into compliance with changes in other applicable law or regulations.

If the plan, previously approved by USDA, needs to be amended because of changes to the State or Tribe's laws or regulations, such resubmissions should be provided to USDA within a calendar year from when the new State or tribal law or regulations are effective. Producers will be held to the requirements of the previous plan until such modifications are approved by

USDA. If State or tribal government regulations in effect under the USDA-approved plan change but the State or tribal government does not resubmit a modified plan within the calendar year of the effective date of the change, USDA will issue a notification to the State or tribal government that approval of its plan will be revoked. The revocation will be effective no earlier than the beginning of the next calendar year. When USDA sends the notification to the State or Tribe, it will accept applications for USDA licenses from producers in the State or territory of the Indian Tribe for 90 days after the notification even if that time period does not coincide with the annual period in which USDA normally accepts applications under § 990.21

USDA has the authority to audit States and Tribes to determine if they are in compliance with the terms and conditions of their approved plans. If a State or Tribe is noncompliant with their plan, USDA will work with that State or Tribe to develop a corrective action plan following the first case of noncompliance. However, if additional instances of noncompliance occur, USDA has the authority to revoke the approval of the State or Tribal plan for one year. USDA believes that one year is sufficient time for a noncompliant State or Tribe to evaluate problems with their plan and make the necessary adjustments. Should USDA determine the approval of a State or Tribal plan should be revoked, such a revocation would begin after the end of the current calendar year, so producers will have the opportunity to adjust their operations as necessary. This one-year window will allow producers to apply for a license under the USDA plan so that their operations do not become disrupted due to the revocation of the State or Tribal plan.

For the 2020 planting season, the 2018 Farm Bill provides that States and institutions of higher education can continue operating under the authorities of the 2014 Farm Bill. The 2018

Farm Bill extension of the 2014 Farm Bill authority expires 12 months after the effective date of this rule.

III. Department of Agriculture Plan

This rule also establishes a USDA plan to regulate hemp production by producers in areas where hemp production is legal but is not covered by an approved State or Tribal plan. All hemp produced outside of States and Tribes with approved plans must meet the requirements of the USDA plan. The requirements of the USDA plan are similar to those under State and Tribal plans.

A. USDA hemp producer license.

1. Application

To produce hemp under the USDA plan, producers must apply for and be issued a license from USDA. USDA will begin accepting applications 30 days after the effective date of this interim rule. USDA is delaying acceptance of applications for 30 days to allow States and Tribal governments to submit their plans first. This is to prevent USDA from reviewing and issuing USDA licenses to producers when there is a likelihood that there will soon be a State or Tribal plan in place and producers will obtain their licenses from the State or Tribe.

While a State or Tribal government has a draft hemp production plan pending for USDA approval, USDA will not issue USDA hemp production licenses to individual producers located in those States or Tribal Nations. Once USDA approves a draft hemp production plan from a State or Tribe, it will deny any license applications from individuals located in the applicable State or Tribal Nation. If USDA disapproves a State or Tribal hemp production plan, individual producers located in the State or Tribal Nation may apply for a USDA hemp production license.

For the first year after USDA begins to accept applications, applications can be submitted any time. For all subsequent years, license applications and license renewal applications must be submitted between August 1 and October 31. For hemp grown outdoors, harvesting usually occurs in the late summer and early fall. This application period is close to or after the harvest season when producers are preparing for the next growing season. USDA requests comments on whether this application period is sufficient. USDA may consider an alternative application window if experience demonstrates the need for one. Having an established application period provides adequate time for USDA to effectively and efficiently review and decide on applications, while also providing producers with a licensing decision well before planting season. All applications must comply with the requirements as described below. The license application will be available online at the USDA Domestic Hemp Production Program website. Applications may be submitted electronically or by mail. Copies can be also requested by email at farbill.hemp@usda.gov.

The application will require contact information such as name, address, telephone number, and email address (if available). If the applicant represents a business entity, and that entity will be the producer, the application will require the full name of the business, address of the principal business location, full name and title of the key participants on behalf of the entity, an email address if available, and EIN number of the business entity.

All applications must be accompanied by a completed criminal history report. If the application is for a business entity, a completed criminal history report must be provided for each key participant.

Key participants are a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes persons in a corporate entity at executive levels including chief executive officer, chief operating officer and chief financial officer. This does not include other management positions like farm, field or shift managers. USDA is requiring a criminal history records report for key participants because those persons are likely to have control over hemp production, whether production is owned by an individual, partnership, or a corporation. USDA considers those individuals to be responsible for ensuring compliance with the regulatory requirements and thereby active participants in the Domestic Hemp Production Program. If those persons have a disqualifying felony, they can no longer participate in the program as provided for by section 297B(e)(3)(B)(i) of the 2018 Farm Bill. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

USDA will not accept criminal history reports completed more than 60 days before the submission of an application, which provides USDA with an expectation that the findings of the report are reasonably current and accurate.

The criminal history report must indicate the applicant has not been convicted of a State or Federal felony related to a controlled substance for the 10 years prior to the date of when the report was completed. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

In addition to providing the information specified, the application will also require license applicants to certify they will adhere to the provisions of the plan.

Once all the necessary information has been provided, applications will be reviewed by USDA for completeness and to determine an applicant's eligibility. USDA will approve or deny license applications unless the applicant is from a State or Tribal Nation that has a plan submitted to or approved by USDA. Applicants will be notified if they have been granted or denied a license either by mail or email.

If an application is denied, the applicant will receive a notification letter or email specifying why the application was denied. If denied, applicants will have the option of resubmitting a revised application if the application was rejected for being incomplete. Applicants may resubmit after October 31 as long as the original application was submitted between August 1 and October 31. If the application was rejected for other reasons, the applicant will have the opportunity to appeal the USDA's decision in accordance with the appeals process outlined in the regulation.

2. USDA Hemp Producer Licenses

Once a license application has been approved, USDA will issue the producer license. Licenses are not transferrable in any manner. An applicant whose application has been approved will not be considered a licensed producer under the USDA plan until the applicant receives their producer license. Licenses do not renew automatically and must be renewed every three years. Because of the felony ban, we believe it is necessary to review producers' criminal history to ensure that they have not committed a felony since the most recent license approval that would disqualify them.

Applications for renewal will be subject to the same terms and approved under the same criteria as initial applications unless there has been an intervening change in the applicable law or regulations since approval of the initial or last application. In such a case the subsequently enacted law or regulation shall govern renewal of the license. Licenses will be valid until December 31 of the year that is at least three years after the license is issued. This date is not tied to the harvest and planting season. Rather it is tied to the window for applications (Aug. 1 – Oct. 31) and the 60 days for USDA to make a decision. For example, if a producer applies for a license August 1, 2020 and is granted a license on September 15, 2020, the license would expire December 31, 2023. A December 31 expiration date will allow licensed producers time to apply for a license renewal prior to their prior license’s expiration and prevent a gap in licensing.

Once a producer has been issued a USDA license, the producer must report their hemp crop acreage to FSA. Producers must provide specific information to FSA, as identified in this part, including, but not limited to: the specific location where hemp is produced, and the acreage, greenhouse, building, or site where hemp is produced. The specific location where hemp is produced must be identified, to the extent practicable, by the geospatial location.

If at any time, there is a change to the information submitted in the license application, a license modification is required. A license modification is required if, for example, the licensed business is sold to a new owner or when hemp will be produced in a new location not described on the original application. Producers must notify USDA immediately should there be any change in the information provided on the license application. USDA will provide guidance on where producers will submit this information on its website.

B. Sampling and testing for THC.

All hemp production must be sampled and tested for THC concentration levels. Samples must be collected by a USDA- approved sampling agent, or a Federal, State or local law enforcement agent authorized by USDA to collect samples. It is the responsibility of the licensed producer to pay any fees associated with sampling. USDA will issue guidance on sampling procedures that will satisfy sampling requirements to coincide with publication of this rule. This guidance will be provided on the USDA website.

The sampling procedures are designed to produce a representative sample for testing. They describe procedures for entering a growing area and collecting the minimum number of plant specimens necessary to accurately represent the THC content, through laboratory testing, of the sample to be tested.

THC levels in representative samples must test at or below the acceptable hemp THC level. Testing will be conducted using post-decarboxylation or other similarly reliable methods where the total THC concentration level measured includes the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) into THC. Further, test results should be determined and reported on a dry weight basis, meaning the percentage of THC, by weight, in a cannabis sample, after excluding moisture from the sample. The moisture content is expressed as the ratio of the amount of moisture in the sample to the amount of dry solid in the sample.

Based on USDA's review of scientific studies, internal research and information gathered from the *United Nations Office on Drugs and Crime: Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products* (ISBN 978-92-1-148242-3), USDA has determined that testing methodologies meeting these requirements include gas or liquid chromatography with detection.

USDA requires that all samples tested for THC concentration levels be conducted in DEA registered laboratories. These laboratories must also meet standards of performance described in this regulation. Standards of performance ensure the validity and reliability of test results, and that analytical method selection, validation, and verification is appropriate (fit for purpose) and that the laboratory can successfully perform the testing. Furthermore, the standards ensure consistent, accurate, analytical performance and that the analytical tests performed are sufficiently sensitive for the purposes of the detectability requirements under this part.

Laboratories who conduct THC testing must also be registered with DEA to handle controlled substances under the CSA and DEA regulations (21 CFR part 1301). USDA is adopting this requirement because of the potential for these laboratories to handle cannabis products testing above 0.3% THC. Such products are, by definition, marijuana, and a controlled substance. DEA registration requirements verify a laboratory's ability to properly handle controlled substances.

As previously explained in the requirements for State and Tribal plans, USDA is also considering requiring that testing for THC concentration levels be conducted in USDA approved laboratories for USDA plan licensees. USDA approved laboratories are authorized under the USDA, AMS, Laboratory Approval Service, which administers the Laboratory Approval Program (LAP). USDA-approved laboratories would need to comply with the LAP requirements, as established under "Laboratory Approval Program - General Policies & Procedures" (www.ams.usda.gov/services/lab-testing/lab-approval), which describes the general policies and procedures for a laboratory to apply for and maintain status in a LAP. Under the LAP, an individual program for hemp would be developed, with a set of documented

requirements to capture specific regulatory, legal, quality assurance and quality control, and analytical testing elements. A requirement for a testing laboratory to be approved by USDA would be in addition to the requirement in the final rule that the laboratory be registered with DEA.

USDA is considering a LAP for USDA licensees because it would be tailored to a commodity to meet specific requirements in support of domestic and international trade. In addition to requiring ISO 17025 accreditation, which assesses general competence of testing laboratories, the LAP would provide a way for USDA to certify that laboratories perform to a standard level of quality. This is an important factor, as the issue of providing assurance as to proper testing was raised on numerous occasions during the USDA outreach process conducted prior to developing this rule. The LAP would give USDA the proper oversight of the laboratories doing the testing, providing quality assurance and control procedures that ensure a validated and qualified analysis, and defensible data. Should USDA require that testing laboratories be approved by USDA, a list of USDA approved laboratories would be posted on the USDA Domestic Hemp Production Program website. Although this proposal is not reflected in the regulatory text of this interim rule, USDA is seeking comment on it to determine whether to incorporate it in the subsequent final rule.

Alternatively, USDA is considering requiring all laboratories testing hemp to have ISO 17025 accreditation. We are requesting comment on this requirement as well.

It is the responsibility of the licensed producer to select the DEA-registered laboratory that will conduct the testing and to pay any fees associated with testing. Laboratories performing THC testing for hemp produced under this program will be required to share test results with the

licensed producer and USDA. USDA will provide instructions to all approved labs on how to electronically submit test results to USDA. Laboratories may provide test results to licensed producers in whatever manner best aligns with their business practices, but producers must be able to produce a copy of test results. For this reason, providing test results to producers through a web portal or through electronic mail, so the producer will have ready access to print the results when needed, is preferred.

Samples exceeding the acceptable hemp THC level are marijuana and will be handled in accordance with the procedures discussed in sections C and D below.

Any licensee may request that the laboratory retest samples if it is believed the original THC concentration level test results were in error. The licensee requesting the retest of the second sample would pay the cost of the test. The retest results would be issued to the licensee requesting the retest and a copy would be provided to USDA or its agent.

C. Disposal of non-compliant product.

If the results of a test conclude that the THC levels exceed the acceptable hemp THC level, the approved laboratory will promptly notify the producer and USDA or its authorized agent. If a licensed producer is notified that they have produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of in accordance with the CSA and DEA regulations as such product is marijuana and not hemp. The material must be collected for destruction by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, or local law enforcement officer, or official.

Licensed producers notified they have produced product exceeding the acceptable hemp THC level must arrange for disposal of the lot represented by the sample in accordance with the CSA and DEA regulations as specified above. Specific DEA procedures for arranging for the disposal of non-compliant product will be listed on the USDA Domestic Hemp Production Program website.

Producers must document the disposal of all marijuana. This can be accomplished by either providing USDA with a copy of the documentation of disposal provided by the reverse distributor or by using the reporting requirements established by USDA. These reports must be submitted to USDA following the completion of the disposal process.

D. Compliance.

USDA has established certain compliance requirements for USDA licensees as part of this rulemaking. This includes the ability for USDA to conduct audits of USDA licensees and to issue corrective action plans for negligent violations. Negligent violations by a producer may lead to suspension or revocation of a producer's license.

USDA may conduct random audits of licensees to verify hemp is being produced in accordance with the provisions of this part. The format of the audit will vary and may include a "desk-audit" where USDA requests records from a licensee or the audit may be a physical visit to a licensee's facility. When USDA visits a licensee's facility, the licensee must provide access to any fields, greenhouses, storage facilities or other locations where the licensee produces hemp. USDA may also request records from the licensee to include production and planting data, testing results, and other information as determined by USDA.

USDA will conduct an audit of all USDA licensees no more than every three years based on available resources.

USDA will issue a summary of the audit to the licensee after the completed audit. Licensees who are found to have a negligent violation will be subject to a corrective action plan. A negligent violation includes: (1) failure to provide a legal description of the land on which the hemp is produced; (2) not obtaining a license before engaging in production; or (3) producing plants exceeding the acceptable hemp THC level. Similar to the requirements for State and Tribal plans, USDA will not consider hemp producers as committing a negligent violation if they produce plants exceeding the acceptable hemp THC level if they use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5 percent on a dry weight basis.

For sampling and testing violations, USDA will consider the entire harvest from a distinct lot in determining whether a violation occurred. This means that if testing determines that each sample of five plants from distinct lots has a THC concentration exceeding the acceptable hemp THC level (or 0.5 percent if the hemp producer has made reasonable efforts to grow hemp), USDA considers this as one negligent violation. If an individual produces hemp without a license, this will be considered one violation. USDA will establish and review a corrective action plan with the licensee and its implementation may be verified during a future audit or site visit.

When USDA determines that a negligent violation has occurred, USDA will issue a Notice of Violation. This Notice of Violation will include a corrective action plan. The corrective action plan will include a reasonable date by which the producer will correct the

negligent violation or violations and require the producer to periodically report to USDA on its compliance with the plan for a period of not less than the next two calendar years. A producer who has negligently violated this part three times in a five-year period is ineligible to produce hemp for a period of five years from the date of the third violation. Negligent violations are not subject to criminal enforcement. However, USDA will report the production of hemp without a license issued by USDA to the Attorney General.

Hemp found to be produced in violation of this part, such as hemp produced on a property not disclosed by the licensed producer, or without a license, would be subject to the same disposal provisions as for cannabis testing above the acceptable hemp THC level. Further, if it is determined a violation was committed with a culpable mental state greater than negligence, USDA will report the violation to the Attorney General and the chief law enforcement officer of the State or Tribe as applicable.

The 2018 Farm Bill limited the participation of certain convicted felons in hemp production. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under the Act. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

E. Suspension of a USDA license.

A USDA license may be suspended if USDA or its representative receives credible information that a licensee has either: (1) engaged in conduct violating a provision of this part; or (2) failed to comply with a written order from the AMS Administrator related to a negligent

violation of this part. Examples of credible information are information from local authorities of harvested plants without testing or planting of hemp seed in non-approved locations.

Any producer whose license has been suspended shall not handle or remove hemp or cannabis from the location where hemp or other cannabis was located at the time when USDA issued its notice of suspension without prior written authorization from USDA. Any person whose license has been suspended shall not produce hemp during the period of suspension. A suspended license may be restored after a waiting period of one year. A producer whose license has been suspended may be required to comply with a corrective action plan to fully restore their license.

A USDA license shall be immediately revoked if the licensee: (1) pleads guilty to, or is convicted of, any felony related to a controlled substance;⁷ or (2) made any materially false statement with regard to this part to USDA or its representatives with a culpable mental state greater than negligence; or (3) was found to be growing cannabis exceeding the acceptable hemp THC level with a culpable mental state greater than negligence or negligently violated the provision of this part three times in five years.

If the licensed producer wants to appeal any suspension or revocation decision made by USDA under this section, they can do so using the appeal process specified in section V.

F. Reporting and recordkeeping.

⁷ For a corporation, if a key participant has a disqualifying felony conviction, the corporation may remove that person from a key participant position. Failure to remove that person will result in a license revocation.

The 2018 Farm Bill requires USDA to develop a process to maintain relevant information regarding the farm on which hemp is produced. USDA's FSA is best suited to collect this information for the domestic hemp production program. FSA has staff throughout the United States who are trained to work with farmers to verify land uses. Many hemp producers are likely to be familiar with the FSA since they already operate traditional farms, and therefore already provide data to FSA on acres and crops planted. Consequently, licensed producers will be required to report their hemp crop acreage with FSA, and to provide FSA with specific information regarding field acreage, greenhouse, or indoor square footage of hemp planted. This information must include street address, geospatial location or other comparable identification method specifying where the hemp will be produced, and the legal description of the land. Geospatial location or other methods of identifying the production locations are necessary as not all rural locations have specific addresses. This information is required for each field, greenhouse, building, or site where hemp will be grown. USDA will use this information to assemble and maintain the data USDA must make available in real time to Federal, State, and local law enforcement as required by the 2018 Farm Bill and as specified in section G below. Specific procedures for reporting hemp acreage to FSA will be posted on the USDA Domestic Hemp Production Program website. This information will be maintained by USDA for at least three calendar years.

Licensed producers will be required to maintain copies of all records and reports necessary to demonstrate compliance with the program. These records include those that support, document, or verify the information provided in the forms submitted to USDA. Records and reports must be kept for a minimum of three years.

Under the USDA plan, there will be additional reporting requirements for licensed producers. These include specific reporting requirements to collect the information needed by the licensing application, and the record and reporting requirements needed to document disposal of cannabis produced in violation of the provisions of this rule. Specific requirements may be referenced herein at § 990.71.

G. Information sharing.

USDA will develop and maintain a database of all relevant and required information regarding hemp as specified by the 2018 Farm Bill. This database will be accessible in real time to Federal, State, local and Tribal law enforcement officers through a Federal Government law enforcement system. USDA AMS will administer and populate this database, which will include information submitted by States and Tribes, laboratories, information submitted by USDA licensed producers, and information submitted to FSA.

USDA will use this information to create a comprehensive list of all domestic hemp producers. USDA will also gather the information related to the land used to produce domestic hemp. This information will be comprehensive and include data both from State and Tribal plans and include a legal description of the land on which hemp is grown by each hemp producer and the corresponding geospatial location. Finally, USDA will also gather information regarding the status of all licenses issued under State and tribal governments and under the USDA plan.

This information will be made available in real time to Federal, State, local and Tribal law enforcement as required by the 2018 Farm Bill.

USDA has prepared a System of Records Notice (SORN) and a Privacy Impact Analysis to be issued concurrently with this rule.

IV. Definitions

In support of the foregoing regulations and hemp production plan descriptions, USDA is establishing definitions for certain terms. The following terms are integral to implement the 2018 Farm Bill and establish the scope and applicability of the regulations of this part.

The term “Act” refers to the Agricultural Marketing Act of 1946. The 2018 Farm Bill amended the Agricultural Marketing Act of 1946 by adding Subtitle G which is a new authority for the Secretary of Agriculture to administer a national hemp production program. Section 297D of Subtitle G authorizes and directs USDA to promulgate regulations to implement this program.

The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture is the agency the Secretary of Agriculture has charged with the responsibility to oversee the administration of this new program.

The term “applicant” means any State or Indian Tribe that has applied for USDA approval of a State or tribal hemp production plan for the State or Indian Tribe they represent. This term also applies to any person or business in a State or territory of an Indian Tribe not subject to a State or tribal plan, who applies for a hemp production license under the USDA plan established under this part.

The term “cannabis” is the Latin name of the plant that, depending on its THC concentration level, is further defined as either “hemp” or “marijuana.” Cannabis is a genus of flowering plants in the family Cannabaceae of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. For the purposes of this part, Cannabis refers to any form of the plant where the delta-9 tetrahydrocannabinol concentration on a dry

weight basis has not yet been determined. This term is important in describing regulations that apply to plant production, sampling or handling prior to determining its THC content.

The Controlled Substances Act (CAS) is the statute, codified in 21 U.S.C. 801-971, establishing Federal U.S. drug policy under which the manufacture, importation, exportation, possession, use, and distribution of certain substances is regulated. Because cannabis containing THC concentration levels of higher than 0.3 percent is deemed to be marijuana, a schedule I controlled substance, its regulation falls under the authorities of the CSA. Therefore, for compliance purposes, the requirements of the CSA are relied upon for the disposal of cannabis that contains THC concentrations above the stated limit of this part.

The rule includes a definition of “conviction” to explain what is considered a conviction and what is not. Specifically, a plea of guilty or nolo contendere or any finding of guilt is a conviction. However, if the finding of guilt is subsequently overturned on appeal, pardoned, or expunged, then it is not considered a conviction for purposes of part 990. This definition of “conviction” is consistent with how some other agencies who conduct criminal history record searches determine disqualifying crimes.

A “corrective action plan” is a plan set forth by a State, tribal government, or USDA for a licensed hemp producer to correct a negligent violation of or non-compliance with a hemp production plan, its terms, or any other regulation set forth under this part. This term is defined in accordance with the 2018 Farm Bill, which mandates certain non-compliance actions to be addressed through corrective action plans.

“Culpable mental state greater than negligence” is a term used in the 2018 Farm Bill to determine when certain actions would be subject to specific compliance actions. This term

means to act intentionally, knowingly, willfully, recklessly, or with criminal negligence.

The term “decarboxylated” refers to the completion of the chemical reaction that converts THC-acid (THCA) into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of THCA. This term, commonly used in scientific references to laboratory procedures, is the precursor to the term “post-decarboxylation,” a term used in the 2018 Farm Bill’s mandate over cannabis testing methodologies to identify THC concentration levels. This definition is based on the regulations administered by the Kentucky Department of Agriculture as part of the Kentucky industrial hemp research pilot program.

“Delta-9 tetrahydrocannabinol,” also referred to as “Delta-9 THC” or “THC” is the primary psychoactive component of cannabis, and its regulation forms the basis for the regulatory action of this part. As mandated by the Act, legal hemp production must be verified as having THC concentration levels of 0.3 percent on a dry weight basis or below. For the purposes of this part, delta-9 THC and THC are interchangeable.

“DEA” means the “Drug Enforcement Administration,” a United States Federal law enforcement agency under the United States Department of Justice. The DEA is the lead agency for domestic enforcement of the Controlled Substances Act. The DEA plays an important role in the oversight of the disposal of marijuana, a schedule I controlled substance, under the regulations of this part. The DEA is also instrumental in registering USDA-approved laboratories to legally handle controlled substances, including cannabis samples that test above the 0.3 THC concentration level.

“Dry weight basis” refers to a method of determining the percentage of a chemical in a

substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

The Farm Service Agency (FSA) is an agency of the U.S. Department of Agriculture, that provides services to farm operations including loans, commodity price supports, conservation payments, and disaster assistance. For the purposes of this program, FSA will assist in information collection on land being used for hemp production.

“Gas chromatography” or GC, is a scientific method (specifically, a type of chromatography technique) used in analytical chemistry to separate, detect, and quantify each component in a mixture. It relies on the use of heat for separating and analyzing compounds that can be vaporized without decomposition. Under the terms of this part, GC is one of the valid methods by which laboratories may test for THC concentration levels.

For the purposes of this part, “geospatial location” means a location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

This term “handle” is commonly understood by AMS and used across many of its administered programs. For the purposes of this part, “handle” refers to the actions of cultivating or storing hemp plants or hemp plant parts prior to the delivery of such plant or plant part for further processing. In cases where cannabis plants exceed the acceptable hemp THC level, handle may also refer to the disposal of those plants.

“Hemp” is defined by the 2018 Farm Bill as “the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids,

isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

“High-performance liquid chromatography (HPLC) or (LC)” is a scientific method (specifically, a type of chromatography) used in analytical chemistry used to separate, identify, and quantify each component in a mixture. It relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds. Under the terms of this part, HPLC is one of the valid methods by which laboratories may test for THC concentration levels. Ultra-Performance Liquid Chromatography (UPLC) is an additional method that may also be used as well as other liquid or gas chromatography with detection.

“Indian Tribe” is defined in the 2018 Farm Bill by reference to section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304). The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

A “key participant” is a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes persons in a corporate entity at executive levels including chief executive officer, chief operating officer and chief financial officer. This does not include such management as farm, field or shift managers.

“Law enforcement agency” refers to all Federal, State, or local law enforcement agencies. Under the 2018 Farm Bill, State submissions of proposed hemp production plans to USDA must

be made in consultation with their respective Governors and chief law enforcement officers. Moreover, the 2018 Farm Bill contemplates the involvement of law enforcement in compliance actions related to offenses identified as being made under a “culpable mental state.” To assist law enforcement in the fulfillment of these duties, the 2018 Farm Bill also mandates an information sharing system that provides law enforcement with real-time data.

The term “lot” refers to a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout. In addition, “lot” is a common term in agriculture that refers to the batch or contiguous, homogeneous whole of a product being sold to a single buyer at a single time. Under the terms of this part, “lot” is to be defined by the producer in terms of farm location, field acreage, and variety (i.e., cultivar) and to be reported as such to the FSA.

As defined in the CSA, “marihuana” (or “marijuana”) means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. The term ‘marihuana’ does not include hemp, as defined in section 297A of the Agricultural Marketing Act of 1946, and does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (7 U.S.C. 1639o(1)). “Marihuana” also means all cannabis that tests as having a concentration level of THC on a dry weight basis of higher than 0.3 percent.

“Negligence” is a term used in the 2018 Farm Bill to describe when certain actions are

subject to specific compliance actions. For the purposes of this part, the term means failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part.

Used in relation to the other terms and regulations in this part, "phytocannabinoids" are cannabinoid chemical compounds found in the cannabis plant, two of which are Delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD). Testing methodologies under this part will refer to the presence of "phytocannabinoids" as either THC or CBD.

Under the terms of this program, "plan" refers to a set of criteria or regulations under which a State or tribal government, or USDA, monitors and regulates the production of hemp. "Plan" may refer to a State or Tribal plan, whether approved by USDA or not, or the USDA hemp production plan.

The 2018 Farm Bill mandates that all cannabis be tested for THC concentration levels using "postdecarboxylation" or similar methods. In the context of this part, "postdecarboxylation" means testing methodologies for THC concentration levels in hemp, where the total potential delta-9-tetrahydrocannabinol content, derived from the sum of the THC and THCA content, is determined and reported on a dry weight basis. The postdecarboxylation value of THC can be calculated by using a chromatograph technique using heat, known as gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. The result of this test calculates total potential THC. The postdecarboxylation value of THC can also be calculated by using a high-performance liquid chromatograph technique, which keeps the THCA intact, and requires a conversion calculation of that THCA to calculate total potential THC. See also the definition for decarboxylation.

The term “produce,” when used as a verb, is a common agricultural term that is often used synonymously with “grow” and means to propagate plants for market, or for cultivation for market, in the United States. In the context of this part, “produce” refers to the propagation of cannabis to produce hemp.

The 2018 Farm Bill mandates that USDA maintain a real-time informational database that identifies registered hemp production sites, whether under a State, tribal, or USDA plan, for the purposes of compliance and tracking with law enforcement. AMS will maintain this system with the information collection assistance of FSA. In order to maintain consistency and uniformity of hemp production locations, USDA is recommending that FSA collect this information through their crop acreage reporting system. In this context, a common use of the term “producer” is essential to maintaining a substantive database. For this reason, the definition of “producer” incorporates the FSA definition of “producer” with the additional qualifier that the producer is licensed or authorized to produce hemp under the Hemp Program.

“Secretary” means the Secretary of Agriculture of the United States.

Section 297A of the Act defines “State” to mean any of one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

This term “State department of agriculture” is defined by the 2018 Farm Bill as the agency, commission, or department of a State government responsible for agriculture in the State. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The term “store” is part of the term “handle” under this part and means to deposit hemp plants or hemp plant product in a storehouse, warehouse or other identified location by a producer for safekeeping prior to delivery to a recipient for further processing.

As defined by the 2018 Farm Bill, the term “tribal government” means the governing body of an Indian Tribe. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The “U.S. Attorney General” is the Attorney General of the United States.

“USDA” is synonymous with the United States Department of Agriculture.

In the context of this part, “licensee” or “USDA licensed hemp producer” means a person or business authorized by USDA to grow hemp under the terms established in this part and who produces hemp.

V. Appeals

An applicant for a USDA hemp production program license may appeal a license denial to the AMS Administrator. Licensees may appeal denials of license renewals, license suspensions, or license revocations to the AMS Administrator. All appeals must be submitted in writing and received within 30 days of the denial. This submission deadline should provide adequate time to prepare the necessary information required to formulate the appeal. States or Tribes may appeal USDA decisions either denying, suspending or revoking State or Tribal hemp production plans. As with the USDA license plans, these appeals must be submitted in writing to the AMS Administrator and explain the reasoning behind the appeal, e.g. why the Administrator’s decision is not justified or is improper. The appeal should include any additional information or documentation the appellant or licensee believes USDA should

consider when reviewing its decision. The Administrator will take into account the applicant or licensee's justification for why the license should not be denied, suspended, or revoked, and then issue a final determination. Determinations made by the Administrator under the appeals process will be final unless the applicant or licensee requests a formal adjudicatory proceeding to review the decision, which will be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H. If the applicant or licensee does not request that the Administrator initiate a formal adjudicatory proceeding within 30 days of the Administrator's adverse ruling, such ruling becomes final. The following paragraphs explain when and how a State or Tribe may appeal a USDA decision. State or Tribal plans may include similar appeal procedures; this following section is not applicable to individuals subject to State or Tribal plans.

Appeals under a State or Tribe hemp production plan

A State or Tribe may appeal the denial of a proposed hemp production plan, or the proposed suspension or revocation of a plan by the USDA. USDA will consult with States and Tribes to help ensure their draft plans meet statutory requirements, and that existing plan requirements are monitored and enforced by States and Tribes. If, however, a proposed State or Tribal plan is denied, or an existing plan is suspended or terminated, the decision may be appealed.

If the AMS Administrator sustains a State or Tribe's appeal of a denied hemp plan application, the proposed State or Tribal hemp production plan shall be established as proposed. If the AMS Administrator denies an appeal, prospective producers located in the State or Tribe may apply for hemp licenses under the terms of the USDA hemp production plan. Similarly, if

an appeal to a proposed State or Tribal plan revocation is denied, producers located in the impacted State or Tribal territory may apply for licenses under the USDA plan.

The appeal of a State or Tribal hemp production plan suspension or termination must explain the reasoning behind the appeal and be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. This timeframe should be adequate for the assembly of the information required to be submitted as part of the appeal.

VI. Interstate commerce

Nothing in this rule prohibits the interstate commerce of hemp. No State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with this part and with section 7606 of the 2014 Farm Bill through the State or the territory of the Indian Tribe, as applicable.⁸

VII. Outreach

As part of this rulemaking process, USDA engaged in numerous discussions with industry stakeholders prior to issuing this rule. This included numerous meetings with different State and tribal groups and representatives, industry organizations, groups and individuals with experience in the hemp industry, and representatives of law enforcement.

In addition, USDA also conducted a listening session on March 13, 2019, that had more than 2,100 participants, and included comments from 46 separate speakers representing States,

⁸ See section 10114 of the 2018 Farm Bill and the USDA General Counsel's Legal Opinion on the Authorities for Hemp Production at <https://www.ams.usda.gov/content/legal-opinion-authorities-hemp-production>.

Tribes, producers, end-users, hemp organizations, and others. The recording of the listening session is available on the USDA website. On May 1 and 2, 2019, USDA also participated in tribal consultation meetings.

As required by the Farm Bill, the Secretary has developed these regulations and guidelines in consultation with the Attorney General. In addition, USDA will submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate containing updates on the implementation of the hemp requirements in the Farm Bill.

VIII. Severability

This interim rule includes a severability provision. This is a standard provision in regulations. This section provides that if any provision of part 990 is found to be invalid, the remainder of the part shall not be affected.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), through this document AMS announces its intent to request approval from OMB for a new information collection OMB No. 0581-NEW and comments are invited on this new information collection. All comments received on this information collection will be summarized and included in the final request for OMB approval.

Based on our review of the hemp production under the 2014 Farm Bill, we estimate that there will be approximately 6,700⁹ producers under State and Tribal plans, approximately 1,000 producers under the USDA plan, and 100 State and Tribal plans. We estimate that each producer will have an average of two lots of hemp with most producers growing one lot per year but larger producers growing many different lots. Each lot will need to be tested for THC concentration.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Domestic Hemp Production Program; 7 CFR 990

OMB Number: 0581-NEW

Type of Request: New Collection

Abstract: The proposed information collection and reporting requirements will facilitate the effective administration and oversight of the Domestic Hemp Production Program, as described above. The Hemp Program includes provisions, among others, requiring licensed

⁹ The 6,700 figure represents the average number of growers operating under State and Tribal plans over the three years of the program. In actuality, we estimate 5,500 such growers in 2020, 6,700 growers in 2021 and 8,000 growers in 2022 who will participate through State and Tribal programs.

producers to maintain information on the land where hemp is produced, hemp testing for delta-9 tetrahydrocannabinol, and disposal of plants not meeting necessary requirements. Additionally, as explained above, all licensed producers must report hemp crop acreage to the USDA Farm Service Agency (FSA). The licensed producer must maintain information that supports, verifies, or documents information on all reports for a minimum of three years. This includes, but is not limited to, the producer's completed criminal history report, any records of required disposal, notifications of THC test results, and the license. This new information collection proposes to create seven new forms. These forms will be available on the USDA domestic hemp website, or copies can be requested from farbill.hemp@usda.gov. AMS is in the process of building a database for applicants and producers to submit applications and reports. The forms and information collected on those forms are described below. The information reported for data collected under State and Tribal plans incorporates the burden to producers licensed under State and Tribal plans associated with providing the required information.

State and Tribal Hemp Producer Report. Every State or Tribe with an approved plan must provide AMS with information on the hemp producers covered under their plan using the State and Tribal Hemp Producer Report form. States and Tribes are required to submit this information to USDA not later than 30 days after the date it is received using this report. This report should be submitted to USDA on the first day of each month. If this date falls on a holiday or weekend, the report is due the next business day. This information should be submitted to USDA using a digital format compatible with USDA's information sharing systems, whenever possible.

If there are no changes from the previous reporting cycle, States and Tribes could check the box indicating there were no changes during the current reporting cycle. This information will be collected and maintained by USDA and made available in real time to Federal, State, and local law enforcement. States and Tribes will need to retain the information used to populate this form for three calendar years.

State and Tribal Hemp Producer Report

Estimate of Burden: Public burden for States and Tribes completing and maintaining this form is estimated to be an average of 0.34 hours per response.

Respondents: States and Tribes with USDA approved hemp production plans

Estimated Number of Respondents: 100

Estimated Number of Responses per Respondent: 12

Estimated Total Annual Responses: 1,200

Estimated Total Annual Hours per Respondent: 0.333 hours

Estimated Total Annual Reporting Hours: 400 hours (rounded)

Estimated Number of Record Keepers: 100

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 8.3 hours

Estimated Total Annual Burden Hours (Including 8.3 hours): 408.3 hours

Information and Record Keeping for State and Tribal Producer Report Responses

Estimate of Burden: Public burden for State and Tribal producers providing and maintaining the information for this form is estimated to be an average of 0.25 hours per response.

Estimated Number of Respondents: 8,000

Estimated Number of Responses per Respondent: 0.3330

Estimated Total Annual Responses: 2,664

Estimated Total Annual Hours per Respondent: 0.167 hours

Estimated Total Annual Burden Hours: 444.9 hours (2,664 X 0.1670 hours (10 mins))

Estimated Number of Record Keepers: 2,664

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 221.1 hours

Estimated Total Annual Burden and Record Keeping Hours for State and Tribal Producer

Responses (Including 221.1 hours): 666 hours

State and Tribal Hemp Disposal Report: States or Indian Tribes operating under approved hemp production plans must notify USDA of any occurrence of non-conforming plants or plant material and provide the disposal record of those plants and materials monthly. This includes plants or plant material which test above the acceptable hemp THC level or hemp otherwise produced in violation of this part. This information should be submitted to USDA using a digital format compatible with USDA's information sharing systems, whenever possible.

State and Tribal Hemp Disposal Report

Estimate of Burden: Public burden for the States and Tribes completing and maintaining this form is estimated to be an average of 0.34 hours per response.

Respondents: States and Tribes with USDA approved hemp production plans

Estimated Number of Respondents: 100

Estimated Number of Responses per Respondent: 12

Estimated Total Annual Responses: 1,200

Estimated Total Annual Hours per Respondent: 0.333 hours

Estimated Total Annual Reporting Hours: 400 hours (rounded)

Estimated Number of Record Keepers: 100

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 8.3 hours

Estimated Total Annual Burden Hours (including the 8.3 hours): 408.3 hours

Information and Record Keeping for State and Tribal Producer Report Responses

Estimate of Burden: Public burden for State and Tribal producers providing and maintaining the information for this form is estimated to be an average of 0.25 hours per response.

Estimated Number of Respondents: 2,680

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Responses: 2,680

Estimated Total Annual Hours per Respondent: 0.167 hours

Estimated Total Annual Burden Hours: 447.6 hours

Estimated Number of Record Keepers: 2,680

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 222.4 hours

Estimated Total Annual Burden and Record Keeping Hours for State and Tribal Producer

Responses (Including 222.4 hours): 670 hours

State and Tribal Hemp Annual Report: Each year, AMS is required to provide an annual report to Congress regarding the implementation Subtitle G of the AMA. In order to ensure that AMS has the best available information on U.S. hemp production to populate this report, AMS is requiring States and Tribes to submit an annual report to AMS. This report includes a summary for all hemp planted, destroyed, and harvested under each State or Tribe’s hemp production plan. States and Tribes would submit this information to USDA using the “State and Tribal Hemp Annual Report” form annually by December 15.

State and Tribal Hemp Annual Report

Estimate of Burden: Public burden for completing and maintaining the information on this form is estimated to be an average of 0.42 hours per response.

Respondents: States and Tribes with USDA approved hemp production plans

Estimated Number of Respondents: 100

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Responses: 100

Estimated Total Annual Hours per Respondent: 0.333 hours

Estimated Total Annual Reporting Hours: 33.3 hours

Estimated Number of Record Keepers: 100

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 8.3 hours

Estimated Total Annual Burden Hours (including the 8.3 hours): 41.6 hours

Information and Record Keeping for State and Tribal Producer Report Responses

Estimate of Burden: Public burden for completing and maintaining the information for this form is estimated to be an average of 0.25 hours per response.

Estimated Number of Respondents: 6,700

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Responses: 6,700

Estimated Total Annual Hours per Respondent: 0.167 hours

Estimated Total Annual Burden Hours: 1,118.9 hours

Estimated Number of Record Keepers: 6,700

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 556.10 hours

Estimated Total Annual Burden and Record Keeping Hours for State and Tribal Producer Responses (Including 556.1 hours): 1675 hours

USDA Hemp Producer Licensing Application: To obtain a license from USDA, producers would need to complete the “USDA Hemp Plan Producer Licensing Application” form. This form will collect the information identified in §990.21. By signing the application, the applicant would certify, should they become a licensed producer, they would abide by all rules and regulations relating to the USDA plan, and to the truth and accuracy of the information provided in the application.

For the first application cycle, USDA will accept license applications for the first year after the effective date of the rule. After this initial period, license applications must be submitted between August 1 and October 31 of each year. Licenses do not renew automatically and must be renewed every three years. Applications for license renewal would be subject to the same terms and approved under the same criteria as initial license applications, unless there has been an intervening change in the applicable law or regulations since approval of the initial or last application. In such a case, the subsequently enacted change in law or regulation shall govern renewal of the license. Licenses will be valid until December 31 of the year three after the year in which license is issued. For example, if you apply for a license August 1, 2020 and are granted a license on September 15, 2020, the license would expire December 31, 2022. The license application will be available online at the USDA domestic hemp production program website, or copies can be requested by email at farbill.hemp@usda.gov. Applications may be submitted electronically or through U.S. mail.

USDA Hemp Plan Producer Licensing Application

Estimate of Burden: Public burden for completing and maintaining this form is estimated to be an average of 0.25 hours per response.

Respondents: Producers applying for the USDA plan

Estimated Number of Respondents: 1,000

Estimated Number of Responses per Respondent: 0.3333

Estimated Total Annual Responses: 333

Estimated Total Annual Hours per Respondent: 0.167 hours

Estimated Total Annual Reporting Hours: 55.6 hours

Estimated Number of Record Keepers: 333

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 27.7 hours

Estimated Total Annual Burden Hours (including the 27.7 hours): 83.3 hours

USDA Hemp Plan Disposal Notification: Producers licensed by USDA must test hemp prior to harvest, dispose of all non-compliant cannabis plants, and report to USDA disposal of all non-compliant cannabis plants. Producers must document the disposal of all marijuana in accordance with §990.27. Reporting can be accomplished by either providing USDA with a copy of the documentation of disposal provided by the reverse distributor or by submitting a “USDA Hemp Plan Producer Disposal Form” to document the disposal process.

USDA Hemp Plan Producer Disposal Form

Estimate of Burden: Public burden for completing and maintaining this form is estimated to be an average of 0.42 hours per response.

Respondents: Producers covered under the USDA plan

Estimated Number of Respondents: 400

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Responses: 400

Estimated Total Annual Hours per Respondent: 0.333 hours

Estimated Total Annual Reporting Hours: 133.3 hours

Estimated Number of Record Keepers: 400

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 33.3 hours

Estimated Total Annual Burden Hours (including the 33.3 hours): 166.6 hours (rounded)

End of Year Harvest Reporting Requirements: The Farm Bill requires AMS to prepare and submit an annual report to Congress on the implementation of the domestic hemp production program. To ensure AMS has adequate planting, production, and harvest data necessary for this report, we are requiring producers to submit an annual harvest report. Each producer would need to submit to USDA an annual report of their total acreage planted, harvested, and, if applicable, disposed. If a producer has multiple growing and harvesting cycles throughout the year (e.g., greenhouse and producers in warm climates) they should all be summarized and submitted on this form. Producers would submit this information to USDA using the “USDA Hemp Plan Producer Annual Report” form by December 15 each year.

USDA Hemp Plan Producer Annual Report

Estimate of Burden: Public burden for completing and maintaining this form is estimated to be an average of 0.42 hours per response.

Respondents: Producers applying for the USDA plan

Estimated Number of Respondents: 1,000

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Responses: 1,000

Estimated Total Annual Hours per Respondent: 0.333 hours

Estimated Total Annual Reporting Hours: 333.3 hours

Estimated Number of Record Keepers: 1,000

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 83.3 hours

Estimated Total Annual Burden Hours (Including the 83.3 hours): 416.6 hours rounded

Report of Acreage: Producers shall report name, address, license or authorizing number, geospatial location for each lot or greenhouse where hemp will be produced and hemp crop acreage to FSA. This will establish an identification system for hemp production nationwide and complies with the information sharing requirements of the 2018 Farm Bill

Report of Acreage FSA 578

Estimate of Burden: Public burden for completing and maintaining this form is estimated to be an average of 0.58 hours per response.

Respondents: Producers under State, Tribal or the USDA plan

Estimated Number of Respondents: 7,700

Estimated Annual Number of Responses per Respondent: 1

Estimated Total Annual of Responses: 7,700

Estimated Total Annual Hours per Respondent: 0.5 hours

Estimated Total Annual Reporting Hours: 3,850

Estimated Number of Record Keepers: 7,700

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 639.1 hours

Estimated Total Annual Burden Hours (Including the 639.1 hours): 4,489.1 hours

Laboratory Test Results Report: The Farm Bill requires that all domestically produced hemp be tested for total THC content on a dry weight basis. All test results, whether passing, failing, or re-tests must be reported to USDA.

Laboratory Test Results Report

Estimate of Burden: Public burden for completing and maintaining this form is estimated to be an average of 1.08 hours per response.

Respondents: Laboratories testing hemp for THC content

Estimated Number of Respondents: 7,700

Estimated Annual Number of Responses per Respondent: 2

Estimated Total Annual of Responses: 15,400

Estimated Total Annual Hours per Respondent: 0.5 hours

Estimated Total Annual Reporting Hours: 7,700

Estimated Number of Record Keepers: 7,700

Estimated Total Annual Hours per Record Keeper: 0.083 hours

Estimated Record Keeping Hours: 639.1 hours

Estimated Total Annual Burden Hours (Including the 639.1 hours): 8,339.1 hours

This new information collection assumes 9,100 total respondents, 17,363 burden hours, and annual costs of \$989,714.94. This is calculated by multiplying the mean hourly wage of \$57 by 17,363 hours. The mean hourly wage of a compliance officer, as reported in the May 2018 Occupational Employment Statistics Survey of the Bureau of Labor and Statistics, was \$35 per hour. Assuming 39 percent of total compensation accounts for benefits, assumed total compensation of a compliance officer is \$57 per hour.

Total Respondents, Burden Hours and Costs for Each New Form.

FORM	TOTAL BURDEN HOURS FOR EACH FORM	COST FOR EACH FORM	TOTAL RESPONDENTS FOR EACH FORM	TOTAL COST PER RESPONSE
State and Tribal Hemp Producer Report (State and Tribal Responses)	408.26	\$ 23,270.82	100	\$ 232.71
State and Tribal Hemp Producer Report (Producer Responses)	666	\$ 37,962.00	8,000	\$ 4.75
State and Tribal Hemp Disposal Report (State and Tribal Responses)	408.26	\$ 23,270.82	100	\$ 232.71
State and Tribal Hemp Disposal Report (Producer Responses)	670	\$ 38,190.00	2,680	\$ 14.25
State and Tribal Hemp Annual Report (State and Tribal Responses)	41.6	\$ 2,372.91	100	\$ 23.73
State and Tribal Hemp Annual Report (Producer Responses)	1,675	\$ 95,475.00	6,700	\$ 14.25
USDA Hemp Plan Producer Licensing Application (Producer Responses)	83.25	\$ 4,745.25	1,000	\$ 4.75
USDA Hemp Producer Disposal Form	166.52	\$ 9,491.64	400	\$ 23.73
USDA Hemp Producer Annual Report (Producer Responses)	416.3	\$ 23,729.10	1,000	\$ 23.73
Report of Acreage (Producer Responses)	4,489.10	\$ 255,878.70	7,700	\$ 33.23
Laboratory Test Results Report	8,339.10	\$ 475,328.70	7,700	\$ 61.73
	17,363.4	\$ 989,714.94		

E-Government Act

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. We recognize using an electronic system will promote efficiencies in developing and implementing the new USDA Domestic Hemp Production Program. Since this is a new program, AMS is working to make this process as effective and user-friendly as possible.

Civil Rights Review

AMS has considered the potential civil rights implications of this rule on minorities, women, and persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities who are subject to these regulations. This interim rule does not require affected entities to relocate or alter their operations in ways that could adversely affect such persons or groups. Further, this rule would not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

A 60-day comment period is provided to allow interested persons to respond to this interim rule. All written comments received in response to this rule by the date specified will be considered.

Executive Order 13132 Federalism

AMS has examined the effects of provisions in the interim final rule on the relationship between the Federal Government and the States, as required by Executive Order 13132 on "Federalism." Our conclusion is that this rule does have federalism implications because the rule has substantial direct effects on States, on the relationship between the national government and States, and on the distribution of power and responsibilities among the various levels of government. The federalism implications of the rule, however, flow from and are consistent with the underlying statute. Section 297B of the AMA, 7 U.S.C. 1639p, directs USDA to review and approve State plans that meet statutory requirements and to audit a State's compliance with

its State plans. Overall, the final rule attempts to balance both the autonomy of the States with the necessity to create a Federal framework for the regulation of hemp production.

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of States will be imposed ". . . only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." Section 297B of the AMA is the statutory authority underlying the rules for USDA to review, approve, disapprove, or revoke State plans for hemp production. Until the passage of the 2018 Farm Bill, hemp was a schedule I controlled substance as it fell within the CSA definition of marijuana. When hemp was exempted from the definition of marijuana as part of the 2018 Farm Bill, in connection with removing it from that list, Congress established a national regulatory framework for the production of hemp. Because cannabis plants with a THC level higher than 0.3 are marijuana and on the Federal controlled substances list, ensuring that hemp produced under this program is not marijuana is of national significance.

In addition to establishing a national regulatory framework for hemp production, Congress expressly preempted State law with regard to the interstate transportation of hemp. Section 10114 of the 2018 Farm Bill States that "[n]o State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable." Thus, States and Indian Tribes may not prevent the movement of hemp through their States or territories even if they prohibit its production.

Congress also expressly preempted a State's ability to prosecute negligent violations of its plan as a criminal act in section 297B(e)(2)(c). That preemption is incorporated into this rule.

Section 3(d)(2) of the E.O. 13132 requires the Federal Government to defer to the States to establish standards where possible. Section 4(a), however, expressly contemplates preemption when there is a conflict between exercising State and Federal authority under Federal statute. Section 297C of the AMA requires State plans to include six practice and procedures and a certification. It also expressly states that it does not preempt a State's ability to adopt more stringent requirements or to prohibit the production of hemp. Section 297D of the AMA requires USDA to promulgate regulations to implement subtitle G of the AMA which includes section 297B. Subpart B of the final rule repeats those requirements, providing more detail where necessary. States have wide latitude to develop the required practice and procedures. Subpart B includes more details on the testing and sampling of hemp plants to establish a national standard to determine whether the plants meet the statutory definition of hemp. Likewise, the final rule requires States to follow DEA requirements for disposal of marijuana for cannabis plants exceeding the acceptable hemp THC level. Finally, the interim final rule also reaffirms that States may adopt more stringent standards and prohibit hemp production within their jurisdiction.

Section 6 of E.O. 13132 requires consultation with State officials in development of the regulations. AMS conducted significant outreach with State officials including individual meetings, participation in conferences with State officials, and listening session where State officials from all States were invited. During our consultation with the States, representatives from various State agencies and offices expressed the following concerns about sampling and

testing procedures. Most requested that USDA adopt uniform, national requirements to facilitate the marketing of hemp. Some States advocated that USDA defer to each State to determine the appropriate procedures for its plan. USDA recognizes the value of a national standard to promote consistency while allowing States the flexibility to adopt procedures that fit their circumstances. As explained above, USDA is adopting performance standards for sampling and testing. As long as the procedures in the State plans meet those standards, AMS will find those procedures acceptable.

As AMS implements this new program, we will continue to consult with State officials to obtain their feedback on implementation. We encourage States to submit comments on this interim final rule during the comment period which closes on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Finally, we have considered the cost burden that this rule would impose on States as discussed in the Regulatory Impact Analysis of this document.

AMS has assessed this final rule in light of the principles, criteria, and requirements in Executive Order 13132. We conclude that this final rule: is not inconsistent with that E.O.; will not impose significant additional costs and burdens on the States; and will not affect the ability of the States to discharge traditional State governmental functions.

E.O. 13175 Consultation and Coordination with Indian Tribal Governments

AMS has examined the effects of provisions in the final rule on the relationship between the Federal Government and Tribal governments, as required by E.O. 13175 on "Consultation and Coordination with Indian Tribal Governments." We conclude that the final rule does have substantial direct effects on tribal governments, on the relationship between the national

government and tribal governments, and on the distribution of power and responsibilities among the various levels of government. The effects of the rule, however, flow from and are consistent with the underlying statute. Section 297B of the AMA, 7 U.S.C. 1639p, directs USDA to review and approve Tribal plans that meet statutory requirements and to audit a tribal government's compliance with its Tribal plans. Overall, the final rule attempts to balance both the autonomy of the tribal governments with the necessity to create a Federal framework for the regulation of hemp production.

As with State plans, tribal governments will have wide latitude in adopting the required procedures including adopting requirements that are more stringent than the statutory ones. For reasons stated above in the federalism analysis, AMS is adopting national standards for sampling, testing, and disposal of non-compliant plants that Tribal plans must adhere to.

AMS has conducted extensive outreach to tribal governments. On May 1 and 2, 2019, USDA held a formal tribal consultation on the 2018 Farm Bill including a session on hemp production. In addition to the listening sessions for the general public, USDA hosted one for tribal governments following the formal tribal consultation on May 2, 2019. USDA officials attended meetings with representatives of tribal governments.

During those outreach events, tribal representatives from several Tribal Governments expressed their opinion that the 2018 Farm Bill permitted the USDA Secretary to allow AMS to approve Tribe plans ahead of issuing regulations of the USDA plan. Approving plans immediately would allow those Tribes (and States) with a plan to begin planting for the commercial production of hemp in 2019. The USDA Secretary released a Notice to Trade (NTT) on February 27, 2019 to explain that tribal and State plans would not be reviewed or

approved until AMS finalized regulations ahead of the 2020 planting season. Additionally, the NTT stated that until regulations were in place, States, Tribes, and institutions of higher education can continue operating under authorities of the 2014 Farm Bill. The 2018 Farm Bill extension of the 2014 authority expires 12 months after USDA has established the plan and regulations required under the 2018 Farm Bill. A second Notice to Trade was issued on May 27, 2019 to clarify again that Tribal governments through the authorities in the 2014 Farm Bill are permitted grow industrial hemp for research purposes during the 2019 growing season. USDA appreciates the urgency in which the Indian Tribes wish to engage in this new economic opportunity. We have worked expeditiously to develop and promulgate this interim final rule so that States and Tribes will be able to submit their plans in time for the 2020 season.

Some tribal representatives stated that the Act requires that the tribal plans have the specified practice and procedures and USDA is not authorized to evaluate them as part of the review and approval process. We note that the statute requires that USDA approve plans that include procedures that meet the statutory requirements. For example, section 297B(a)(2)(A)(iii) required a procedure for effective disposal and USDA must evaluate whether the plan's procedure is effective.

Although Indian Tribes will incur costs in complying with final rule, those costs should be outweighed by the benefits that the Indian Tribes realize in commercial hemp production occurring within their territories.

Executive Orders 12866, 13563, and 13771

USDA is issuing this rule in conformance with Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if

regulation is necessary, to select regulatory approaches that maximize net benefits, which include potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This rule meets the definition of an economically significant regulatory action under Executive Order 12866, as it is likely to result in an annual effect on the economy of \$100 million or more. USDA considers this to be a deregulatory action as it allows the development of a niche market that cannot exist under current regulation. This action will expand production options and enable interested farmers to grow hemp.

USDA requests public comment on the estimated impacts of the rule, specifically whether there is information or data that may inform whether or not the market will experience a significant shift, either positive or negative, in the developing hemp market and on consumers. In addition, USDA seeks comments and requests any data or information on what impacts the regulation may have on current and future innovation in the areas of industrial hemp usages and how much such impacts on innovation may affect rural communities.

Regulations must be designed in the most cost-effective manner possible to obtain the regulatory objective while imposing the least burden on society. This rule would establish a national regulatory oversight program for the production of hemp. This program is necessary to effectuate the Farm Bill mandate to coordinate State and tribal government hemp production regulations with the newly established Federal regulations for hemp production in States not regulated by State or Tribal plans. This program is intended to provide consistency in

production, sampling and testing of hemp product to ensure compliance with the acceptable hemp THC level.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. The discussion on E.O. 13132, Federalism, above, addressed the extent in which the 2018 Farm Bill and the interim rule preempt State law. The discussion on E.O. 13179, Consultation and Coordination with Tribal governments, above, addresses the impact that the interim rule impacts tribal governments. The discussion above regarding appeals under new part 990, subpart D, describes the administrative procedures that must be exhausted prior to a judicial challenge.

Regulatory Impact Analysis/Initial Regulatory Flexibility Analysis

Introduction

The future of the hemp industry in the United States (U.S.) is anything but certain. While hemp was produced previously in the U.S. for hundreds of years, its usage diminished in favor of alternatives. Hemp fiber, for instance, which had been used to make rope and clothing, was replaced by less expensive jute and abaca imported from Asia. Ropes made from these materials were lighter and more buoyant, and more resistant to salt water than hemp rope, which required tarring. Improvements in technology further contributed to the decline in hemp usage. The cotton gin, for example, eased the harvesting of cotton, which replaced hemp in the manufacture of textiles.¹⁰

¹⁰ Presentation to USDA by Dr. Eric Walker, Assistant Professor in the Department of Plant Sciences at the University of Tennessee, on May 21, 2019.

Hemp production in the U.S. has seen a massive resurgence in the last five years; however, it remains unclear whether consumer demand will meet the supply. From 2017 to 2018, acreage planted for hemp tripled, reaching 77,844 acres. Hemp planted acreage in 2018 was eight times the acreage planted just two years prior in 2016. Acreage in 2019 is expected to at least double from 2018.¹¹

High prices for hemp, driven primarily by demand for use in producing CBD, relative to other crops, have driven increases in planting. Prices for hemp products vary from source to source. Prices for hemp fiber range from \$0.07 per pound to \$0.67 per pound, and prices for hemp grain or seed range from \$0.65 per pound to \$1.70 per pound. Prices for hemp flowers, in which concentrations of the cannabinoid cannabidiol, or CBD, are located, range from \$3.50 to \$30.00 per pound or more, depending on the CBD content. Producer interest in hemp production is largely driven by the potential for high returns from sales of hemp flowers to be processed into CBD oil. From 2017 to 2018, the number of licensed producers of hemp more than doubled to reach 3,543 producers.

The hemp plant is a varietal of the species *Cannabis sativa*. While belonging to the same species as the plant that produces marijuana, hemp is distinctive from marijuana in its chemical makeup. The marijuana plant contains high levels of the cannabinoid delta-9 tetrahydrocannabinol (THC), which is the chemical that produces psychoactive effects. Hemp may contain no greater than 0.3 percent THC on a dry weight basis.

The 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug

¹¹ Vote Hemp, U.S. Hemp Crop Reports.

Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act). Accordingly, products containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as FDA-regulated products containing any other substance.

Legislative History

The production of hemp has a long history in the United States (U.S.). Prior to the mid-20th century, hemp had been cultivated in the U.S. for hundreds of years to make flags, sails, rope, and paper. The first regulation of hemp occurred in 1937 with the Marihuana Tax Act, which required all producers of the species *Cannabis sativa* to register with and apply for a license from the Federal Government. The “Hemp for Victory” Campaign during World War II promoted production of hemp for rope to be used by U.S. military forces, but at the end of the war, the requirements in the Marihuana Tax Act resumed. In 1970, Congress passed the Controlled Substances Act, granting the Attorney General the authority to regulate production of hemp.

The Agricultural Act of 2014, also known as the 2014 Farm Bill, defined hemp as the plant *Cannabis sativa* L. and any part of that plant with concentrations of THC no greater than 0.3 percent on a dry weight basis. Prior to the 2014 Farm Bill, hemp had never been designated in a Federal law as different from cannabis generally. The 2014 Farm Bill authorized institutions of higher education and State departments of agriculture to allow for cultivation of hemp as part of a pilot program as authorized by State law for research. Research allowed under pilot programs included market research, so hemp was cultivated and sold as inputs into various consumer products under the 2014 Farm Bill. This analysis assumes that such cultivation would

have continued and even expanded in the absence of the 2018 Farm Bill.

Need for Regulation

The Agriculture Improvement Act of 2018, known as the 2018 Farm Bill, removed hemp from the list of controlled substances, decontrolling hemp production in all U.S. States, and in territories of Indian Tribes, unless prohibited by State or Tribal Law. This action eliminates the uncertain legal status at the Federal level of hemp production and allows the U.S. Department of Agriculture (USDA) to provide hemp producers with crop insurance programs, potentially reducing risk to producers and providing easier access to capital. The statute also prohibits interference in the interstate transport of hemp by States, including those States which prohibit hemp production and sales. As a result, hemp producers will have access to nationwide markets. The rule is necessary to facilitate this market by creating a set of minimum standards to ensure that hemp being produced under this program meets all statutory requirements. Moreover, both the declassification of hemp, and the prohibition on interference with interstate transportation apply to hemp that is grown under an approved State or Tribal plan, or under a Federal license. As a result, this regulation facilitates provisions of the Farm Bill that would otherwise be self-implementing.

Overview of the Action

The 2018 Farm Bill granted regulatory authority of domestic hemp production to the State departments of agriculture, Tribal governments, and USDA. States and Tribes must submit to USDA plans which include provisions for maintaining information regarding the land on which hemp is produced, for testing the levels of THC, for disposal of plants that do not meet necessary requirements, and for procedures to ensure compliance with the requirements of the

new part. State and Tribal Plans must be approved by USDA. This rule outlines requirements by which the USDA would approve plans submitted by States and Tribal governments for oversight of hemp production. The 2018 Farm Bill also directs USDA to develop a plan for use by hemp producers in States or Tribes where no State or Tribal Plan has been approved and which do not prohibit the cultivation of hemp. These actions will promote consistency in regulations governing the legal production of hemp across the country.

Baseline Definition

In order to measure the impacts of this rule on affected entities, AMS defines the baseline such that sales of hemp products from 2014 through 2019 will be treated as attributable to the 2014 Farm Bill only. While the 2018 Farm Bill permits commercial production of hemp, and the 2014 Farm Bill permits production of hemp for research purposes only, AMS assumes some of the increasing trend of U.S. hemp production would have continued under the provisions of the 2014 Farm Bill in the absence of the 2018 Farm Bill. AMS assumes, therefore, that only 50 percent of the growth in sales of hemp products from 2020 and beyond will be attributable to the 2018 Farm Bill. This assumption considers the rate at which hemp acreage has increased in recent years, the number of States whose hemp pilot programs produced a crop in recent years, and the number of States which have passed legislation following the signing of the 2018 Farm Bill in anticipation of this rule's enactment in time for the 2020 growing season. As this rule enables the 2018 Farm Bill, 50 percent of the growth in sales of hemp products beginning in 2020 will be attributable to this rule.

The 2018 Farm Bill provided that States, Tribes, and institutions of higher education may continue to operate under the authorities of the 2014 Farm Bill for the 2019 planting season.

Under the 2018 Farm Bill, the authority of the 2014 Farm Bill expires one year from the time that USDA establishes the plan and regulations required under the 2018 Farm Bill. As this will occur in the fall of 2019, growers could continue to grow hemp under the provisions of the 2014 Farm Bill in the 2020 planting season. For the purpose of this analysis, however, AMS defines the 2020 planting season as the first year of this rule's impact, with 50 percent of the growth in sales in 2020 being counted as attributable to the 2018 Farm Bill and this enabling rule. This analysis considers the impact of this rule on affected entities from 2020 to 2022. This analysis utilizes hemp market data from industry associations, state departments of agriculture, and universities.

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Affected Entities

Hemp producers in States and territories of Indian Tribes that allow for hemp production will be impacted by this rule.

State departments of agriculture and Tribal governments will also be affected by this rule. State departments of agriculture and Tribal governments will bear the responsibility to ensure that hemp producers abide by the State and Tribal plans for regulating hemp. Prior to the passage of the 2018 Farm Bill, at least 40 States had enacted hemp legislation.¹² With the passage of the 2018 Farm Bill, nearly all of the remaining U.S. States have followed suit. Discussions with State departments of agriculture that currently oversee hemp pilot programs indicate that the authorization requirements for growing hemp for research purposes are similar to those included in State Plans submitted to USDA for approval. The 2018 Farm Bill, however,

¹² Vote Hemp, 2017 U.S. Hemp Crop Report.

includes greater requirements for authorization than what the 2014 Farm Bill mandated, such as information sharing and a criminal history report for licensees. States that oversaw pilot programs under the 2014 Farm Bill, therefore, will likely need additional resources to run the State programs under the 2018 Farm Bill. States and Indian Tribes that did not have a pilot program under the 2014 Farm Bill and that submit plans to USDA for a program under the 2018 Farm Bill may require hiring of new staff to oversee the program. States and Tribes will also be subject to reporting and recordkeeping requirements resulting from this rule. If a State or Tribe chooses not to develop its own plan, then hemp producers within that State or Tribe may utilize the plan developed by USDA, unless prohibited by State or Tribal Law.

Regulatory Impact Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives when an action is deemed to have significant impacts. If regulation is necessary, then agencies must select the action that maximizes net benefits, including potential economic, environmental, public health and safety effects, and equity.

Executive Order 13771 mandates that agencies provide the best approximation of total costs associated with a new or repealed regulation. AMS has prepared this Regulatory Impact Analysis with the purpose of accomplishing these objectives.

USDA considers this to be a deregulatory action under Executive Order 13771 as it allows for the development of a niche market that cannot exist under current regulation. This rule removes barriers to entry and enables domestic farmers to grow hemp.

Expected Benefits and Costs of the Rule

The 2018 Farm Bill grants authorization for production of hemp to all States and Indian

Tribes, unless prohibited by State or Tribal Law. This rule enables States, Tribes, and USDA to regulate this authorization. This rule is expected to generate benefits and costs to hemp producers and State departments of agriculture and Tribal governments. The benefits of this rule are expected to outweigh the costs, however, and the burden on the impacted entities is anticipated to be minimal.

Benefits and Costs of Production

Farmers grow hemp for three products: floral material, fiber, and grain. Based on data from State departments of agriculture and from surveys by the National Industrial Hemp Regulators, a working group comprised of industrial hemp program managers from State departments of agriculture, AMS estimates that about two-thirds of hemp acreage planted is for floral material, while the remaining third is divided evenly between fiber and grain.

The nascent market for industrial hemp causes estimates of yield and price for hemp products to vary widely from source to source. Table 1 shows a range of potential gross revenues received by producers using ranges of yield and price estimates from Vote Hemp, the University of Kentucky, the Kentucky Department of Agriculture, and the Congressional Research Service.¹³ Using low and high estimates for yield and price from these sources, AMS calculated a potential range of gross revenue to producers of hemp products of \$2,443 per acre to \$25,682 per acre.

¹³ Vote Hemp, U.S. Hemp Crop Report available at <https://www.votehemp.com/u-s-hemp-crop-report/>

¹³ Mark, Tyler and Shepherd, Jonathan, Hemp & Enterprise CBD Budget Model available at <http://hemp.ca.uky.edu/>

¹³ Johnson, Renee, Hemp as an Agricultural Commodity, Congressional Research Service, June 2018

Product	Planted acre	Low yield/acre	High yield/acre	Low price/lb.	High price/lb.	Low gross revenue	High gross revenue
Flowers	2/3	1,000	1,200	\$ 3.50	\$ 30.00	\$ 2,333	\$ 24,000
Fiber	1/6	2,000	11,000	\$ 0.07	\$ 0.67	\$ 23	\$ 1,228
Grain	1/6	800	1,600	\$ 0.65	\$ 1.70	\$ 87	\$ 453
Estimated gross revenue received by producers per acre of hemp						\$ 2,443	\$ 25,682
Sources: Vote Hemp; University of Kentucky, Industrial Hemp Budget 2019; Kentucky Department of Agriculture; Congressional Research Service, Defining Hemp: A Fact Sheet.							

Variable costs per acre to producers, as estimated by the University of Kentucky, are shown in Table 2. These variable costs are weighted by the portion of planted acreage for each product as estimated in Table 1. The result is a weighted variable cost of \$19,421 to produce one acre of hemp products.

Product	Variable costs	Planted acre	Variable costs weighted by planted acre portion
Flowers	\$ 28,638	2/3	\$ 19,092
Fiber	\$ 1,077	1/6	\$ 180
Grain	\$ 898	1/6	\$ 150
Total			\$ 19,421
Source: University of Kentucky, Industrial Hemp Budget 2019.			

To estimate producer returns above variable cost, the weighted variable cost per acre is subtracted from the low and high estimates of gross revenue per acre under the scenario of lowest yield and lowest price received per acre and the scenario of highest yield and highest price received per acre. Under the low estimate of gross revenue per acre, a hemp producer who plants two-thirds of an acre for flowers, and the remaining one-third acre split between fiber and grain loses \$16,978 per acre. Under the high estimate of gross revenue per acre, a hemp producer sees a return of \$6,260 above variable costs. It is important to consider that fixed costs are not included among these estimates; therefore, net returns will likely be lower than these

results.

In addition to the previously-mentioned variable costs to grow hemp, AMS considered the opportunity costs to the hemp producer of crops that may have otherwise been planted. Using data from the National Agricultural Statistics Service (NASS), AMS calculated an average gross return per acre of cropland, weighted by area planted or bearing, of \$591. This estimate represents the potential revenue per acre of the crop that a potential hemp producer foregoes to plant hemp instead of other crops including traditional field crops. However, hemp may also attract new producers not currently growing other crops. Subtracting this opportunity cost from the average gross revenue per acre (discussed in more detail below) yields a net social benefit estimate of approximately \$2,060 per acre. For individual growers, however, returns may vary widely – and even be negative.

The per acre net return estimates are based largely on crop enterprise budgets which represent expected costs and returns assuming the grower actually brings a crop to market. There are many things that can preclude actually bringing a planted crop to market including; loss due to weather, pests, or disease, reduced output due to inexperience with the crop, and growing a crop that exceeds the acceptable hemp THC level.

The gross social benefit of the crop is best represented by what customers are willing to pay for the crop. To generate a social benefit per acre, we looked at data from the 2018 Processor/Handler Production Reports to the Kentucky Department of Agriculture. In 2018 Kentucky farmers were paid \$17.75 million for harvested hemp materials from 6,700 planted acres. This results in a societal willingness to pay (assuming Kentucky is sufficiently representative of the United States) of around \$2,650 per acre. Using this average accounts for

acres with unusually high returns as well as acres with low or no returns.

So, while individual growers may see returns ranging from a loss of \$17,578 to a return of \$5,669 per acre, society can expect a benefit of \$2,058 ($=\$2,650-\591) per acre.

Estimated Number of Producers

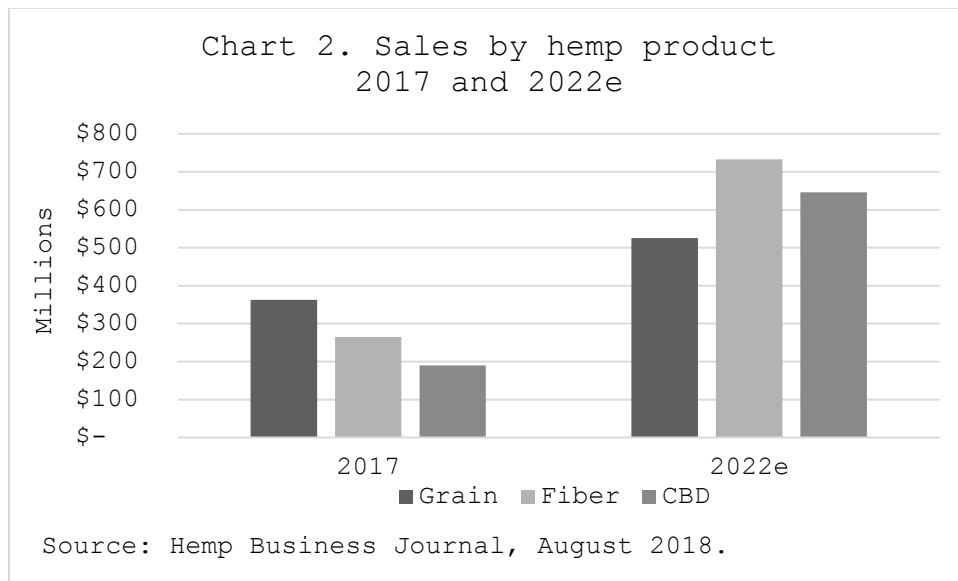
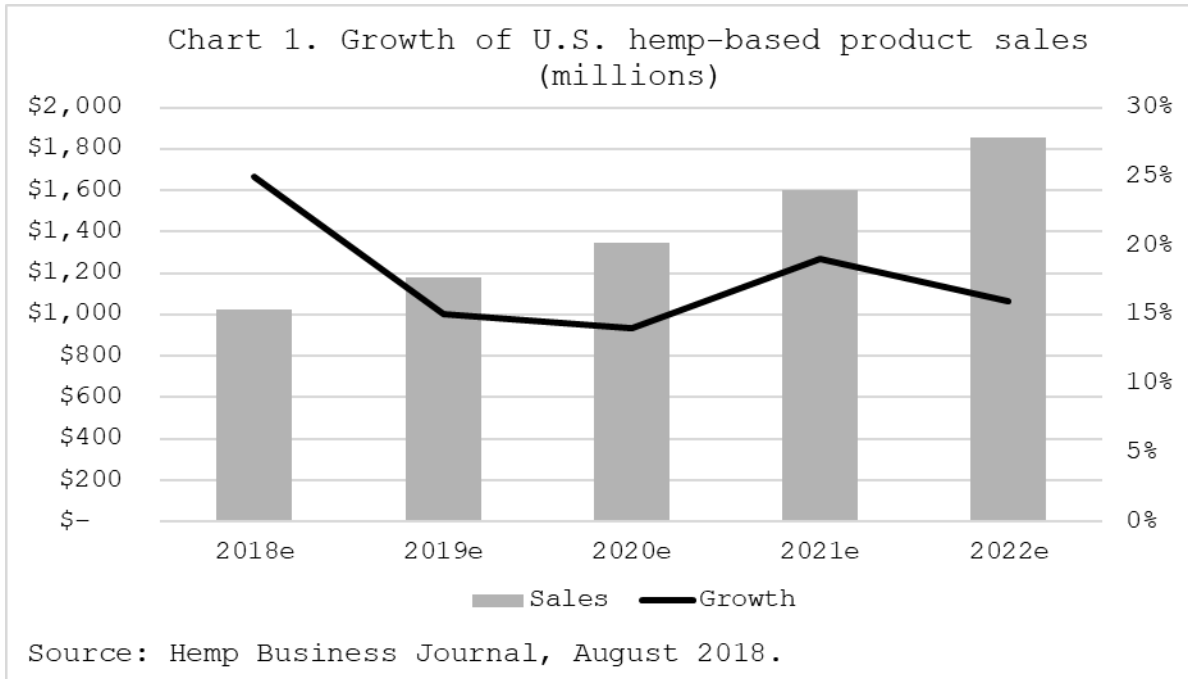
In each year since the 2014 Farm Bill, the number of licensed producers and the amount of acreage planted has increased substantially. According to Vote Hemp, there were a total of 3,543 producer licenses issued by States in 2018, up from 1,456 in 2017, and 817 licenses in 2016. Planted acreage in 2018 was 77,844 acres, up from 25,723 in 2017, and 9,649 acres in 2016. No official estimates of hemp planted acreage, or the number of producer licenses exist for 2019 as of yet; however, industry members agree that 2019 planted acreage will likely at least double acreage planted in 2018. If this occurs, then hemp planted acreage will reach almost 160,000 acres in 2019. See Table 3 below. This increase in acreage is likely due in part to new producers entering the market and in part to current producers expanding their acreage.

Based on data from the State departments of agriculture in Colorado, Kentucky, and Oregon, which together make up 47 percent of planted acreage and 45 percent of producer licenses nationwide, average planted acreage per producer is 24 acres. Assuming that all 77,844 additional acres in 2019 are planted by new producers entering the market, and that each one plants the average of 24 acres, then 2019 should see approximately 3,244 new producers. This is a reasonable assumption given the growth in licenses year over year. Based on this, there should be approximately 6,787 U.S. hemp producers in 2019, as shown in Table 3. For purposes of this analysis, we expect the number of producers to increase at the same rate as increased hemp sales as discussed below.

Table 3. Number of producer licenses and planted acreage, 2016-2019e				
	2016	2017	2018	2019e
Number of licenses	817	1,456	3,543	6,787
Planted acres	9,649	25,723	77,844	155,688

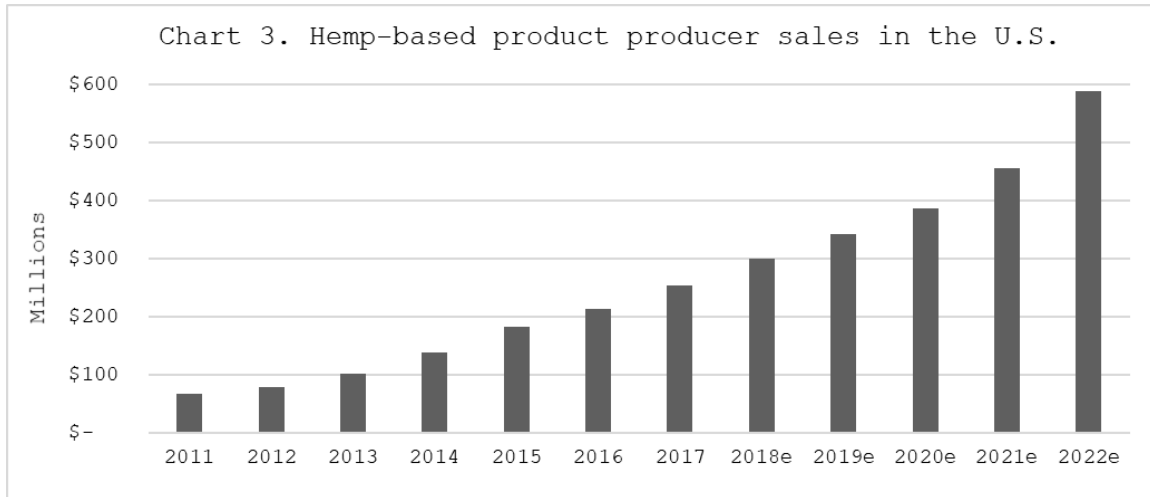
Projected Growth in Gross Revenues

The Hemp Business Journal estimates sales of U.S. hemp-based products from 2018 to 2022. The growth rates of these sales from year to year are shown in Chart 1. It is important to remember that even though the 2018 Farm Bill removed hemp from the list of controlled substances, it preserved the authority of the Food and Drug Administration (FDA) to regulate products which contain cannabis. Sales of hemp-based products are expected to increase about 15 percent from 2018 to 2019. In 2020, sales are expected to grow about 14 percent, in 2021, 19 percent, and in 2022, 16 percent. While these growth rates represent consumer sales and may not necessarily accurately depict the state of the hemp market at the producer level, these estimates are the best available to AMS at this time. Although certain cannabis-derived compounds are generally prohibited to be added to food and dietary supplements, because of their status as pharmaceutical ingredients, the FDA has authority to issue a regulation allowing the use of such ingredients in food and dietary supplements. FDA has stated that they are actively considering this issue. If FDA does not provide clarity about their plans for future regulation of CBD, there will continue to be uncertainty and downward pressure on the CBD portion of the hemp market. This is important because the Hemp Business Journal estimates appear to assume that there are no prohibitions on adding CBD to consumer products. As a result, full realization of the benefits estimated here could be delayed pending regulatory certainty.



Data from the 2018 Processor/Handler Production Reports to the Kentucky Department of Agriculture also show that gross sales by processors reached \$57.75 million in 2018. Of this, gross returns to farmers was approximately 31 percent of total processor gross sales. Applying

31 percent to the consumer sales estimates in the chart above provides an estimate of gross producer returns (and social willingness to pay) over the next four years.



If gross producer returns are 31 percent of total consumer sales, estimated total producer returns in 2018 were approximately \$315 million. In 2019, estimated total producer returns will be approximately \$362 million, in 2020, approximately \$413 million, in 2021, approximately \$491 million, and in 2022, approximately \$570 million. Not all of the producer sales in Chart 3 are the direct result of this rule, however. The forecasts shown in Chart 1 were published by the Hemp Business Journal in the summer of 2018, before the 2018 Farm Bill was passed by Congress. This indicates that the hemp market was expected to grow regardless of the hemp provisions in the 2018 Farm Bill.

Total costs for State licensing, sampling, and testing under the pilot programs generally amounted to about \$1,000 per producer. This includes administration of certified seed schemes in certain States. Measurable impacts to the hemp industry resulting from this rule will not occur until 2020. It is difficult to estimate the increase in total returns to producers as a result of this rule. AMS estimates that this rule is responsible for as much as 50 percent of the increase in

total producer returns from year to year. This assumption considers the rate at which hemp acreage has increased in recent years, the number of States whose hemp pilot programs produced a crop in recent years, and the number of States which have passed legislation following the signing of the 2018 Farm Bill in anticipation of this rule's enactment in time for the 2020 growing season.

Because we would expect hemp production to continue to grow under preexisting State programs, we do not believe it is appropriate to attribute all production growth beyond 2020 to this rule. Since roughly half of the States had operating programs in 2018, we assumed that half of future projected growth could have occurred in the absence of this rule. Based on the total estimated producer returns, AMS estimates that increases in hemp sales directly resulting from the rule will be approximately \$25.5 million in 2020, \$64.5 million, cumulative, in 2021, and \$104 million, cumulative, in 2022. Media reports about the 2018 Farm Bill's approach to hemp seem to indicate that there may be future innovation that would increase producer returns and investment. We request comment about the potential for innovation and the uncertainty and its impact on the market vis a vis steady state.

Costs of State and Tribal Plans

Under most State pilot programs administered under the 2014 Farm Bill, hemp producers paid fees to State departments of agriculture for State licenses to grow hemp, and for sampling and testing of THC content. These fees generally fully fund the program's operation and are a reasonable proxy for the costs to States of administering a plan. Total costs for State licensing, sampling, and testing under the pilot programs generally amounted to about \$1,000 per producer. Discussions with State departments of agriculture that oversee hemp pilot programs indicate that

the provisions for growing hemp for research purposes will be similar to those in the State Plans submitted to USDA for approval. While the 2018 Farm Bill added additional requirements for growing hemp that were not in the 2014 Farm Bill, it is difficult to determine how these additional requirements will impact fees for licensing, sampling, and testing paid by producers to States. For the purpose of this analysis, AMS finds that a cost of \$1,000 per producer is the most reasonable estimate of these annual fees and, by extension the cost to States and Tribes of administering a regulatory program. We have no reason at this time to assume that the Federal government will be any more or less efficient at implementing the Federal program for producers who operate under a USDA license rather than a State or Tribal program. The Federal plan does not require licensed producers to use certified seed, nor will USDA provide producers with access to certified seed. Accordingly, we use this same \$1,000 estimate as a proxy for the cost of administering a program by the Federal Government as well.

In addition to these fees, a producer bears the burden of gathering the information for and filling out an application for licensing. AMS estimates that the time required of a producer to apply for a license to grow hemp will be approximately 10 minutes or 0.17 hours. The mean hourly wage of a compliance officer, as reported in the May 2018 Occupational Employment Statistics Survey of the Bureau of Labor and Statistics, was \$35 per hour. Assuming 39 percent of total compensation accounts for benefits, total compensation of a compliance officer is \$57 per hour. Multiplying this wage by the time spent to complete a license application results in an annual burden cost to producers of about \$10 per license application.

State departments of agriculture and Tribal governments will likely need to increase their staff to successfully oversee hemp programs. States with pilot programs typically employ about

four full-time staff members to manage their industrial hemp programs. The estimated increase in hemp acreage in 2019 indicates a likely increase in licenses and applications; therefore, States with hemp programs may need to hire additional employees. States and Tribes without hemp pilot programs under the 2014 Farm Bill that have their own plans in place under the 2018 Farm Bill will also need to hire new staff members. The fees paid by producers to States and Tribes to participate in the hemp program will likely cover the staffing costs.

Costs of USDA Plan

AMS has developed a Federal Plan for hemp producers to utilize when their State or Tribe does not have its own plan in place. The Federal Plan requires an initial application for a license. The license must then be renewed every three years. A criminal history report is required with every license application. The costs to a producer of completing a license application and of submitting a criminal history report will be quantified in the “Costs of Reporting and Recordkeeping” section. The Federal Plan also includes sampling and testing provisions, which will result in costs to producers. USDA will bear the costs of program administration and does not intend to charge producers a licensing fee unless Congress provides the authority to USDA to charge fees for this program in the future. On average, the annual fee that producers paid to States to participate in the pilot programs, which included licensing, was \$1,000 per license. This will be used as a proxy for the cost to USDA of program administration.

Sampling and testing costs under the Federal Plan are tied to acreage and how licensees designate the lots where hemp is grown. Projected costs for sampling and testing an average 24-acre lot are summarized in Table 4.

Table 4. Costs to hemp producers of sampling and testing under the Federal Plan assuming an average 24-acre lot						
Estimates	Sampling					
	Hourly wage	Time (hrs)	Avg drive time (hrs)	Avg mileage	Mileage rate (\$/mile)	Total cost
Low	\$ 152	0.5	2	107.5	\$ 0.58	\$ 443
High	\$ 152	1	2	108	\$ 0.58	\$ 520
Estimates	Testing				Grand total per tested sample per lot	
	Hourly wage	Time (hrs)	Testing & reporting	Total cost		
Low	\$ 161	0.5	\$ 75	\$ 155	\$ 599	
High	\$ 161	1	\$ 150	\$ 311	\$ 830	

The hourly total compensation, which includes wage and benefits, for a federally-contracted inspector who conducts sampling is \$152, and the hourly total compensation for a federally-employed lab technician who tests the sample is \$161. The standard rate for reimbursement for miles driven at the Federal level is \$0.58 per mile. With information from State departments of agriculture, AMS calculated a range of time spent on sampling, and an average of time spent driving and miles driven by an inspector to and from the sampling location. The range of time spent on testing and of costs for testing and reporting were calculated using input from licensing and testing specialists within AMS. Depending upon the quality of the sample taken and the time spent on sampling and testing, the total cost of sampling and testing to a producer ranges from \$599 to \$830 per tested sample per 24-acre lot. AMS notes that transportation costs are fixed under this analysis assuming all lots tested are at the same farm. If a producer grows multiple varieties of hemp, or designates multiple lots of hemp with the same variety, then each lot is subject to individual sampling and testing. Total sampling and testing costs, therefore, depend upon the number and size of lots.

Costs of Reporting and Recordkeeping

The 2018 Farm Bill requires AMS to prepare and submit an annual report containing updates on the implementation of the domestic hemp production program to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate. To help collect the information necessary to complete this report, and to collect additional information, as necessary, to administer the hemp program, AMS has developed seven new forms. These forms require specific information be submitted by States and Tribes operating their own domestic hemp plans, from producers participating in the USDA Plan, and from laboratories testing for THC content. The annual burden in time and cost has been evaluated for each form. These time and cost figures have been approximated to the nearest whole number.

Respondents: States and Tribes operating their own plans

States and Tribes with approved plans are required to report certain information to USDA. USDA will collect this information from States and Tribes through three forms: the “State and Tribal Hemp Producer Report” form, the “State and Tribal Hemp Disposal Report” form, and the “State and Tribal Hemp Annual Report” form. AMS estimates that the time required of States and Tribes to fill in the information for each of these forms will be 20 minutes or 0.33 hours. The time required of producers to supply the information for the “State and Tribal Hemp Producer Report” form and the “State and Tribal Hemp Disposal Report” form will be 10 minutes, or 0.17 hours, apiece. The “State and Tribal Hemp Producer Report” form and the “State and Tribal Hemp Disposal Report” form are due to USDA every month. The annual time burden for States and Tribes to respond to each of these two forms, therefore, is 4 hours per

respondent. The annual time burden for producers to supply the information for each of these forms will be 10 minutes, or 0.167 hours, per respondent, plus an additional 5 minute recordkeeping burden per form. The “State and Tribal Hemp Annual Report” form must be submitted to USDA once per year; the annual time burden, therefore, remains 0.33 hours per respondent. The “State and Tribal Hemp Annual Report” form is anticipated to place a burden on producers participating in the State and Tribal Plan of 15 minutes per producer (10 minutes for reporting and 5 minutes for recordkeeping).

Each of these forms required from States and Tribes is expected to generate a recordkeeping burden of 5 minutes or 0.08 hours, apiece, per recordkeeper. Altogether, the annual time burden of reporting and recordkeeping per State and Tribe operating under its own plan is estimated to be 9 hours. The mean hourly wage of a compliance officer, as reported in the May 2018 Occupational Employment Statistics Survey of the Bureau of Labor and Statistics, was \$35 per hour. Assuming 39 percent of total compensation accounts for benefits, total compensation of a compliance officer is \$57 per hour. Multiplying this by 9 hours results in a total annual burden cost to each State and Tribe operating under its own plan of \$490. AMS estimates that 100 States and Tribes will operate under their own plans. The annual burden for these 100 States and Tribes of reporting and recordkeeping is 858 hours costing \$49,046 per year.

The information necessary for States and Tribes to submit the “States and Tribal Hemp Producer Report comes from the information supplied by producers in their license applications. AMS estimates that 8,000 producers will submit license applications over three years. AMS estimates a cost of approximately \$10 per license application (based on approximately 10

minutes of burden). These costs will not occur uniformly over the three years as both new and existing processors will need to provide this information in the first year of the program. As result, AMS estimates a cost to producers operating under State and Tribal plans of \$55,000 in 2020, \$12,000 in 2021, and \$13,000 in 2022 – or an average cost of \$27,000 per year.

In addition, producers will be required to prove that they do not have prior drug related convictions that would disqualify them from participation in the program. States have some flexibility in what they require of applicants to make this demonstration. However, for purposes of this analysis, we will use the same cost for States and Tribes that we use for USDA licensees, which is \$54 per licensee. This results in estimated costs of \$291,000 in 2020, \$65,000 in 2021, and \$70,000 in 2022 – or an average cost of \$142,000.

Additionally, AMS estimates that an average of 2,680¹⁴ producers will supply information to States and Tribes for the “State and Tribal Hemp Disposal Report” form each year at an estimated cost of \$38,000 per year.

The total average annual burden on producers to supply information to States and Tribes associated with these two reports will be 1,169 hours, with an estimated cost (including criminal history information) of \$230,000.

In addition, growers of crops that test above the acceptable hemp THC level are responsible for the proper disposal of those non-compliant crops. While the rule makes the producer responsible for the costs of this disposal, such disposal represents a real expenditure of

¹⁴ There is no way to know for certain how many samples will test beyond the 0.3 percent threshold for THC on a dry-weight basis; however, based on information discussions with States that have a hemp program under the 2014 Farm Bill, AMS estimates that 20 percent of lots per year will produce cannabis that tests high for THC content.

societal resources; as such they are a cost of the rule irrespective of who is directly responsible for those costs. The opportunity cost of lost sales is already incorporated in our calculation of benefits since our average benefits per acre are based on total sales and total planted acres and non-compliant acres (which have zero value as hemp) are included in the average expected benefit. However, the additional physical costs of disposal are not represented in the calculation of benefits. As a result, we need to calculate the additional cost imposed by the disposal requirement,

We have no information on the cost of disposing of non-compliant hemp. So, we developed an assumed disposal cost of \$200 per acre based on the estimated cost of the physical activities related to disposal. According to the University of Kentucky crop enterprise budgets for hemp, the cost of harvesting and transporting hemp grown for fiber is roughly \$100 per acre¹⁵. We double this amount to account for the likelihood that there will be additional oversight and documentation required to demonstrate legal disposal. However, we still have no way to estimate any additional cost associated with the physical destruction required after the crop is removed from the farm.

Using this rough cost estimate, the average annual quantified cost of disposal under State and Tribal programs is \$6.432 million.

Respondents: Producers participating in the USDA Plan

To produce hemp under the USDA Plan, a producer, which may be an individual

¹⁵ We used hemp grown for fiber as the basis for our assumption because hemp grown for flower or seed use more refined methods of harvesting that are no longer necessary if the resultant product (flower or seed) no longer has market value.

producer or a business, would need to complete the “USDA Hemp Plan Producer Licensing Application” form and be issued a license. AMS estimates the time required of a producer to fill out this form to be 10 minutes or 0.17 hours. The recordkeeping required for this form is estimated to be 5 minutes, or 0.08 hours. The total burden per respondent of this form is 15 minutes, or .25 hours. Licenses under the USDA Plan must be renewed every three years. Assuming that there will be 1,000 participants in the USDA Plan, AMS estimates that over a three-year period, there will be 667 respondents in each year. The total annual burden for this form, therefore, will be 167 hours with a cost of \$9,541.

In addition to the “USDA Hemp Plan Producer Licensing Application” form to be submitted once every three years, producers must submit criminal history reports for each of their key participants. AMS estimates each producer to have three key participants that would submit criminal history reports to USDA. The cost of a criminal history report is \$18 apiece, which results in a cost of \$54 per participant. As stated previously, AMS estimates that it will receive 333 license renewals in each year over a three-year period. The average annual cost of the criminal history reports that will accompany these renewals is \$17,982 annually.

Similar to the required annual report submitted by States and Tribes to USDA, producers operating under the USDA Plan must submit the “USDA Hemp Plan Producer Annual Report” to USDA each year. AMS estimates the time burden of submitting this form to be 20 minutes, or 0.33 hours. The recordkeeping burden of this form is estimated to be 5 minutes, or 0.08 hours. Together, the burden of this form is 25 minutes, or 0.42 hours, per respondent. AMS estimates 1,000 participants in the USDA Plan. The total burden of this form, therefore, is 417 hours, costing \$23,808 annually.

When a hemp sample tests above the acceptable hemp THC level, the material from the production area which the sample represents must be destroyed by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, or local law enforcement officer or their designee. Producers must document the disposal of all marijuana. This can be accomplished by either providing USDA with a copy of the documentation of disposal provided by the reverse distributor or with the “USDA Hemp Plan Producer Disposal Form”. AMS estimates the time required to complete this form to be 20 minutes, or 0.33 hours, which would be split between the producer and authorized agent who carries out the disposal. The recordkeeping required for this form would amount to 5 minutes, or 0.08 hours, per respondent. The total burden of this form is, therefore, 15 minutes, or 0.25 hours, for a producer, and 10 minutes, or 0.17 hours, for an authorized agent. Together, the burden is 25 minutes, or 0.42 hours, per respondent.

Using the same assumptions regarding the prevalence of non-compliant crops and the costs of disposal that were used in generating the estimates of hemp disposal reporting (and disposal) for State and Tribal programs, the 1,000 producers that will participate in the USDA Plan will generate 400 samples will test high for THC content. The total reporting burden of this form will amount to 167 hours and cost \$9,523 annually. Additionally, producers operating under USDA licenses are expected to incur quantified disposal costs of \$960,000 annually.

Altogether, the annual burden of the “USDA Hemp Plan Producer Licensing Application”, the “USDA Hemp Plan Producer Disposal Form”, and the “USDA Hemp Plan Producer Annual Report” amounts to an annual total of 666 hours and a cost of \$37,962. Adding in the criminal history report cost brings the total to \$55,962 annually.

Respondents: Laboratories

The Farm Bill requires that all domestically produced hemp be tested for total THC content on a dry-weight basis, whether produced under a State or Tribal Plan or the USDA Plan. To facilitate this, AMS is requiring all laboratories testing hemp for THC to submit all test results, whether passing or failing, via the “Laboratory Test Results Report”. AMS estimates this form to generate a total annual reporting burden of 30 minutes, or 0.5 hours, per test or submitted form, and a total annual recordkeeping burden of 5 minutes, or 0.08 hours, per producer. Together, the reporting and recordkeeping burden for this form is 35 minutes, or .58 hours.

There is no way to know for certain how many tests laboratories will conduct in a single year and how many of them will be subject to re-testing. AMS estimates, however, that laboratories will receive two samples representing two lots of hemp material from 7,700 producers, resulting in 15,400 tests annually. The total annual burden of these tests and the accompanying “Laboratory Test Results Report” form is, therefore, 8,399 hours, and costs of \$478,743.

Respondents: All producers

The Farm Service Agency (FSA) collects information on crop acreage through the “Report of Acreage” form. All hemp producers will be required to fill in the information for this form once they receive their license or authorization from USDA, a State, or Tribe. AMS estimates this form to generate a reporting burden of 30 minutes, or 0.5 hours, and a recordkeeping burden of 5 minutes, or 0.08 hours. AMS assumes that an average of 7,700 producers will respond to this form each year, resulting in a total annual burden of 4,466 hours,

and a cost of \$254,562.

Total reporting and recordkeeping costs for all respondents

Altogether, the annual burden for reporting and recordkeeping for all respondents is 17,362 hours, costing a total of \$989,634 per year. This is the sum of the annual burden of reporting and recordkeeping to States and Tribes operating their own plans, to producers participating in the State and Tribal Plans, to producers participating in the USDA Plan, including the cost of a criminal history report for three key participants, and to laboratories testing samples for THC content.

Alternatives to the Rule

The actions in this rule are mandated by the 2018 Farm Bill, which enables States, Tribes, and USDA to establish rules and regulations for the domestic production of hemp. The statute requires USDA to develop criteria for approval of plans submitted by State and Tribal governments for regulation of domestic hemp production. If no State or Tribal Plan has been approved, then hemp producers in these States or Tribes may utilize the plan developed by USDA. These plans will promote a greater level of consistency in regulations governing the legal production of hemp across the United States.

In developing the sampling procedures for the Federal Plan, AMS considered the protocols for sampling used by State departments of agriculture and by countries that regulate hemp production. In addition, AMS reviewed sampling methods recommended by Codex Alimentarius, which is the central part of the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Food Standards Program and was established by FAO and WHO to protect consumer health and promote fair practices in food trade. After

research and review of multiple sampling protocols, AMS adopted the best option among the alternatives.

The 2018 Farm Bill mandates testing using post-decarboxylation or other similarly reliable methods where the total THC concentration level considers the potential to convert delta-9-tetrahydrocannabinolic *acid* (THC-A) into THC. Testing methodologies meeting these requirements include those using gas or liquid chromatography with detection. These methods are the industry standard for post-decarboxylation testing. While these methods were chosen by AMS as the best option for testing, alternative sampling and testing protocols will be considered if they are comparable to the baseline mandated by the 2018 Farm Bill and established under the USDA Plan and Procedures.

Alternatives to the selected procedures for sampling and testing for THC content included connecting a producer lot of cultivated hemp to a standard unit of measure. AMS considered describing one lot as one acre of hemp. This alternative was abandoned, however, as it would have required every acre of hemp to be sampled and tested, which would have resulted in high costs to producers and overwhelming volume to laboratories.

Net Benefits from the Rule

AMS has provided the approximation of the total costs and benefits associated with this new regulation. Using the costs and benefits introduced in the preceding sections, AMS has calculated the net benefits of this rule in Table 5 using an upper bound estimate of costs. The results shown in Table 5 were calculated using many assumptions. These figures are only estimates using the data that was available to AMS. The absence of industry and government data along with the high degree of uncertainty regarding the future of the hemp market makes

accurately capturing the impact of this rule on the hemp industry an impossible task. Regardless, AMS estimated the net benefits of this rule in years 2020, 2021, and 2022 as shown in Table 5. AMS has also calculated the net benefits of the rule using a lower bound estimate of costs. The results of that analysis are shown in Table 5a. The assumptions used to calculate the lower bound estimate are discussed later in this document.

The costs and benefits associated with this rule will begin in the year 2020. From the signing of the 2018 Farm Bill to the enactment of this rule in time for the 2020 growing season, the domestic hemp market will be in a state of transition as cultivation of hemp moves from research only to commercialization. The hemp industry in 2018 represents the baseline of this analysis, and the first year which will see impacts from this rule is 2020. The time between will be considered a transitional period as the hemp industry adjusts to incorporate the provisions authorized in the 2018 Farm Bill.

The benefits of this rule primarily include producer sales that are estimated to be due to the hemp provisions in the 2018 Farm Bill and this rule which enables those provisions. Gross revenues represent the best proxy for consumer willingness to pay and social benefits.¹⁶ As the demand for and sales of hemp increase over time, the number of licensees is estimated to grow proportionally (for the purposes of this analysis). As a result, we estimate the number of licensees (State, Tribal, or Federal) to increase from roughly 6,494 in 2020 to 7,720 in 2021, to 8,962 in 2022.

¹⁶ We note that if gross willingness-to-pay is presented as a regulatory benefit, then marginal costs of production must be included as a line item in the regulatory cost analysis. An alternative, reduced-form approach would be to include only producer surplus (or the related concept of profits) and consumer surplus in the benefits analysis.

The benefits and cost of this rule are shown in Tables 5 (summarizing upper-bound cost estimates and associated net benefits) and 5a (summarizing lower-bound cost estimates and associated net benefits). In Table 5, the estimated net benefits of this rule amount to a loss of \$4 million in 2020, a benefit of \$23 million in 2021, and a benefit of \$49 million in 2022. As noted previously, this calculation is based on an upper bound estimate of the costs of the rule. This estimate includes costs to all growers, not just the new entrants resulting from the rule. (In other words, we are incorporating a significant amount of cost that would have been incurred by producers even in the absence of this rule.)

Benefits are based on a share of growth being attributable to the rule while the cost calculations include the costs of compliance borne by all producers, including those that are already growing hemp under the 2014 program and those that would expect to grow hemp under that program in the event that USDA did not promulgate this rule. This leads to costs being overstated relative to the benefits calculated. Many of the costs estimated as attributable to this rule actually represent expenditures of resources that would have taken place under the 2014 program.

We did this for two reasons. The first is simply to demonstrate what we think the full cost of a program similar to the one we are promulgating would be. The second is because the specific requirements of this rule may be slightly different from requirements already in place in States operating hemp programs under the 2014 Farm Bill and we did not want to ignore the fact that these changes may have costs. Put another way, producers under the 2014 plan may already have been required to submit license applications, but not applications that were identical to what is being required. The preexisting State requirement may have been more or less costly, but this

assumed that new and existing growers would bear the full cost of providing the information required under this program. Because we believe the 2018 requirements for producers are very similar to the plans already in operation, we think the estimates used to this point represent an upper bound estimate.

We have also developed a lower bound estimate of costs based on applying costs related to the rule only to those producers who would not have produced hemp in the absence of this rule. Requirements for States and Tribes are all new and will remain attributed to the rule. Similarly, the costs associated with producers reporting information to States and Tribes to facilitate State and Tribal reporting requirements will still be attributable to this rule.

The largest changes in estimated costs result from a reduction in the number of acres (and, by extension growers) directly attributable to this rule. In the upper bound cost case we include the transactions cost (e.g. permit application, crop reporting, testing, disposal etc.) to every producer required to produce the \$491 million worth of hemp in 2021 – or 7,700 producers. In the lower bound we recognize that \$362 million of that production is estimated to occur in 2019 before any new rule is published, so only \$129 million could possibly be related to publication of a new rule. We also acknowledge that there were avenues available to further increase production under the 2014 program and that up to half of that \$129 million in increased revenue could occur without this rule. As a result, only \$65 million of that new growth in 2021 is attributable to this rule. It only takes 1,000 new growers to meet this level of increased demand. So, the lower bound is based on the costs associated with those 1,000 growers vs. the 7,700 used in calculating the upper bound.

This alignment of new producers to new growth allows costs and benefits to be measured

relative to a consistent baseline. However, we also acknowledge that this rule will impose costs on entities beyond just those new entrants into the market who supply a portion of the projected growth in demand for hemp. For example, States and Tribes face new reporting requirements under this rule. Those reporting requirements are independent of the number of licensed producers in their programs that produce to meet existing demand as opposed to those who's production is enabled by this rule. So, the reporting burden for States and Tribes is the same in both the upper bound and lower bound estimates. On the other hand, since State administrative costs are directly tied to the number of program participants, those costs to the State only grow as a function of the number of new entrants into the market. As a result, administrative costs for States and Tribes (as well as the Federal Government) are estimated to be significantly lower in the lower bound estimate.

The following is a discussion of how each major cost or benefit category is modified to move from the upper bound estimate to the lower bound estimate.

Both revenues and opportunity cost were already based on only the new acres enabled by the rule, so those estimates do not change.

The estimate of State and Tribal administrative costs will decline. The upper bound cost estimate included the total cost of administering a hemp program. The lower bound recognizes that States and Tribes were already incurring administrative costs associated with existing production and would expect such costs to increase with increased production under the 2014 program. State and Tribal administrative costs would only increase as a result of new entrants directly enabled by the rule. Using 2021 as an example, 7,700 producers are required to produce all \$491 million in projected demand for hemp. However, only 1,000 producers are required to

produce the approximately \$65 million in projected demand attributable to the rule. Some of those producers will operate under State and Tribal programs and some under USDA license. Based on the proportions used in calculating the upper bound cost, we assume 13 percent of growers to be operating under USDA license and 87 percent to be operating under State license. So, of the 7,700 producers operating in 2021 only 870 are expected to be growing under State or Tribal authority to meet demand increases attributable to the rule. So, the estimate of State and Tribal administrative costs goes from \$6.7 million in the upper bound to \$870,000 in the lower bound estimate.

Similarly, we assume that all producers will be subject to some form of licensing. In the upper bound estimate, we attribute all licensing costs to this rule even though we know that most, if not all, States already have some form of licensing as part of their 2014 programs. So, if we only account for the licensing costs of producers enabled under this rule, the upper bound estimate is \$77,000 to \$35,000 in 2021.

Like State and Tribal administrative costs, USDA administrative costs are tied to the number of entrants into the market in response to demand increases that can be fulfilled as a result of the rule. As previously discussed, this is estimated to be 130 producers in 2021 (the 1,000 new producers minus the 870 who register under State or Tribal programs) at a cost of \$130,000.

Like licensing, we expect that most, if not all, State programs already have some form of product testing. As a result, only the testing of acres attributable to this rule should be included in the estimated cost of the rule. This results in a change from the upper bound estimate of \$11.6 million to an estimated lower bound cost of \$1.5 million. It should be noted, however, that

existing sampling and testing regimes may be more or less stringent than the one imposed by this rule. As a result, this rule could impose additional costs, or represent cost savings, on producers not directly enabled by this rule. These cost changes are not reflected in the lower bound estimate.

As previously mentioned the reporting and recordkeeping burden on the States is independent of the number of program participants and is the same in both upper and lower bound estimates. Also, the burden on producers to supply the information required to be reported by the States and Tribes is required of all producers, so the estimate of those costs also remains the same under upper and lower bound estimates.

The reporting burden for producers operating under USDA license, on the other hand is a function of the number of new licensees and the lower bound estimates reflects this smaller number.

The reporting of information to the Farm Services Agency is a new requirement that applies to all producers. As a result, the estimated cost associated with these provisions of the rule are identical in both upper and lower bound estimates. Similarly, the requirement of testing labs to submit information is new and applies to all tests irrespective of whether or not the producer is new as a result of this rule. Laboratory reporting costs are, therefore, also the same in the upper and lower bound estimates.

Like sampling and testing, we assume that existing producers are already required to dispose of non-compliant crops. As a result, the estimated disposal cost (in 2021) goes from \$7.4 million in the upper bound estimate to \$960,000 in the lower bound estimate. Also, like sampling and testing, the validity of the estimate is a function of the relative costs of Federal

disposal requirements relative to existing State disposal requirements. Any change in the costs of disposal (positive or negative) would apply to all producers, not just those new as a result of this rule.

The benefits and cost of this rule using the lower bound cost estimate are shown in Table 5a. The estimated net benefits of this rule amount to \$18 million in 2020, a benefit of \$47 million in 2021, and a benefit of \$79 million in 2022.

The benefits of this rule primarily include producer sales that are estimated to be due to the hemp provisions in the 2018 Farm Bill and this rule which enables those provisions. Gross revenues represent the best proxy for consumer willingness to pay and social benefits.¹⁷ As the demand for and sales of hemp increase over time, the number of licensees is estimated to grow proportionally (for the purposes of this analysis). As a result, we estimate the number of licensees (State, Tribal, or Federal) to increase from roughly 7,584 in 2020 to 8,818 in 2021, to 10,054 in 2022 and beyond.

¹⁷ We note that if gross willingness-to-pay is presented as a regulatory benefit, then marginal costs of production must be included as a line item in the regulatory cost analysis. An alternative, reduced-form approach would be to include only producer surplus (or the related concept of profits) and consumer surplus in the benefits analysis.

Table 5. Estimated aggregate lower bound net benefits, 2020 to 2022

2020e	Producer sales		
		Producers	\$ 25,500,000
	Opportunity Cost		
		Society	\$ (5,700,000)
	State and Tribal Plan administrative costs		
		Producers (through fees)	\$ (5,500,000)
	Licensing application burden		
		Producers	\$ (416,000)
	USDA Plan Administration		
		USDA	\$ (1,000,000)
	Sampling and testing fees (avg)		
		Producers	\$ (9,763,000)
	Reporting and recordkeeping		
		State and Tribal Plan staff	\$ (70,000)
	Producers under State and Tribal Plan	\$ (117,000)	
	Producers under USDA Plan	\$ (35,000)	
	FSA reporting cost	\$ (215,000)	
	Laboratories testing for THC	\$ (400,000)	
	Disposal Cost		\$ (6,240,000)
	NET BENEFITS		\$ (3,956,000)
2021e	Producer sales		
		Producers	\$ 64,500,000
	Opportunity Cost		
		Society	\$ (14,000,000)
	State and Tribal Plan administrative costs		
		Producers (through fees)	\$ (6,700,000)
	Licensing application burden		
		Producers	\$ (77,000)
	USDA Plan Administration		
		USDA	\$ (1,000,000)
	Sampling and testing fees (avg)		
		Producers	\$ (11,565,000)
	Reporting and recordkeeping		
		State and Tribal Plan staff	\$ (70,000)
	Producers under State and Tribal Plan	\$ (134,000)	
	Producers under USDA Plan	\$ (35,000)	
	FSA reporting cost	\$ (255,000)	
	Laboratories testing for THC	\$ (474,000)	
	Disposal Cost		\$ (7,392,000)
	NET BENEFITS		\$ 22,798,000
2022e	Producer sales		
		Producers	\$ 104,000,000
	Opportunity Cost		
		Society	\$ (23,000,000)
	State and Tribal Plan administrative costs		
		Producers (through fees)	\$ (8,000,000)
	Licensing application burden		
		Producers	\$ (83,000)
	USDA Plan Administration		
		USDA	\$ (1,000,000)
	Sampling and testing fees (avg)		
		Producers	\$ (13,518,000)
	Reporting and recordkeeping		
		State and Tribal Plan staff	\$ (70,000)
	Producers under State and Tribal Plan	\$ (152,000)	
	Producers under USDA Plan	\$ (35,000)	
	FSA reporting cost	\$ (298,000)	
	Laboratories testing for THC	\$ (554,000)	
	Disposal Cost		\$ (8,640,000)
	NET BENEFITS		\$ 48,650,000

Table 5a. Estimated aggregate upper bound net benefits, 2020 to 2022

2020e	Producer sales		
		Producers	\$ 25,500,000
	Opportunity Cost		
		Society	\$ (5,700,000)
	State and Tribal Plan administrative costs		
		Producers (through fees)	\$ (348,000)
	Licensing application burden		
		Producers	\$ (23,000)
	USDA Plan Administration		
		USDA	\$ (52,000)
	Sampling and testing fees (avg)		
		Producers	\$ (601,000)
	Reporting and recordkeeping		
		State and Tribal Plan staff	\$ (70,000)
		Producers under State and Tribal Plan	\$ (117,000)
	Producers under USDA Plan	\$ (1,000)	
	FSA reporting cost	\$ (215,000)	
	Laboratories testing for THC	\$ (400,000)	
	Disposal Cost	\$ (384,000)	
	NET BENEFITS	\$ 17,589,000	
2021e	Producer sales		
		Producers	\$ 64,500,000
	Opportunity Cost		
		Society	\$ (14,000,000)
	State and Tribal Plan administrative costs		
		Producers (through fees)	\$ (870,000)
	Licensing application burden		
		Producers	\$ (35,000)
	USDA Plan Administration		
		USDA	\$ (130,000)
	Sampling and testing fees (avg)		
		Producers	\$ (1,502,000)
	Reporting and recordkeeping		
		State and Tribal Plan staff	\$ (70,000)
		Producers under State and Tribal Plan	\$ (134,000)
	Producers under USDA Plan	\$ (6,000)	
	FSA reporting cost	\$ (255,000)	
	Laboratories testing for THC	\$ (474,000)	
	Disposal Cost	\$ (960,000)	
	NET BENEFITS	\$ 46,064,000	
2022e	Producer sales		
		Producers	\$ 104,000,000
	Opportunity Cost		
		Society	\$ (23,000,000)
	State and Tribal Plan administrative costs		
		Producers (through fees)	\$ (1,392,000)
	Licensing application burden		
		Producers	\$ (59,000)
	USDA Plan Administration		
		USDA	\$ (208,000)
	Sampling and testing fees (avg)		
		Producers	\$ (2,403,000)
	Reporting and recordkeeping		
		State and Tribal Plan staff	\$ (70,000)
		Producers under State and Tribal Plan	\$ (152,000)
	Producers under USDA Plan	\$ (10,000)	
	FSA reporting cost	\$ (298,000)	
	Laboratories testing for THC	\$ (554,000)	
	Disposal Cost	\$ (1,536,000)	
	NET BENEFITS	\$ 74,318,000	

The net benefits in each of the three years have been discounted to reflect their present value and annualized. The results of these calculations are presented in Table 6 at using a discount rate of three percent and in Table 6a using a discount rate of seven percent. The final result of this analysis indicates that this rule is estimated to have annual net benefits of between 23 and 47 million dollars at a discount rate of three percent and between 21 and 44 million dollars at a discount rate of seven percent.

Table 6 Annualized Costs, Benefits, and Net Benefit (at 3 percent)		
	Lower Bound	Upper Bound
Benefit	\$65,810,000	\$65,810,000
Cost	\$19,016,000	\$43,172,000
Net Benefit	\$46,794,000	\$22,638,000

Table 6a Annualized Costs, Benefits, and Net Benefit (at 7 percent)		
	Lower Bound	Upper Bound
Benefit	\$62,440,000	\$62,440,000
Cost	\$18,053,000	\$41,283,000
Net Benefit	\$44,386,000	\$21,156,000

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601-612), AMS has considered the economic impact of this action on small entities. AMS has prepared this Regulatory Flexibility Analysis and has determined that this rule will have a

significant economic impact on a substantial number of small businesses because many small businesses will not be able to participate in the hemp market without this rule.

Reasons Action is Being Considered

The Agriculture Improvement Act of 2018 mandates that States and Tribes submit to USDA plans for regulation of hemp to include procedures for information management, testing for THC, and compliance with the regulation. State and Tribal plans must be approved by USDA. If no State or Tribal Plan has been approved, then hemp producers in those States or Tribes may use the plan developed by USDA, unless prohibited by State or Tribal Law.

Potentially Affected Small Entities

The Small Business Administration (SBA) defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than \$750,000. Unfortunately, very little data exists that shows the annual receipts of industrial hemp producers. To conduct this analysis, however, AMS utilized State acreage data and an estimate of gross revenue per acre received by producers calculated using the 2018 Processor/Handler Production Reports to the Kentucky Department of Agriculture. USDA seeks comments on other reliable data sources that may be available.

AMS used State acreage data by producer from three of the four States with the largest amount of licensed acreage to serve as a proxy for the portion of small producers nationwide. Together, Colorado, Oregon, and Kentucky make up about 47 percent of planted acreage and 45 percent of producer licenses nationwide, according to Vote Hemp data. While acreage data by producer was not available for Montana, its State department of agriculture reported that very few hemp operations in Montana received annual receipts in excess of \$750,000 in 2018.

Vote Hemp estimates that on average, about 70 percent of licensed acreage is planted. AMS applied this percentage to 2018 licensed acreage data from Colorado, Oregon, and Kentucky to estimate 2018 cultivated acreage. The estimate of gross revenue per acre to producers of \$3,293 was used to find the number of acres required to generate an annual receipt of \$750,000. The result is shown in Table 7.

Table 7. Hemp producers meeting the SBA definition of a small business in 2018		
Gross revenue per acre	Acreage for annual receipt of \$750,000	Portion of producers considered small by SBA
\$ 3,293	228	99%

With a gross revenue of \$3,293 per acre, a producer with no more than 228 acres would be considered small under SBA standards. Based on this estimate of gross revenue per acre, 99 percent of producers would meet the SBA definition of a small agricultural service firm. “Using estimated costs from the RIA, anticipated costs per entity that want to enter the hemp industry are expected to be about \$2,941 in 2020, and \$2,900 in 2021. However, entry into this market is voluntary and benefits are anticipated to outweigh the estimated costs.”

Alternatives to Minimize Impacts of the Rule

The actions in this rule are mandated by the 2018 Farm Bill, which enables States, Tribes, and USDA to establish rules and regulations for the domestic production of hemp. The statute requires USDA to develop criteria for approval of plans submitted by State and Tribal governments for regulation of domestic hemp production. If no State or Tribal Plan has been approved, then hemp producers in these States or Tribes may utilize the plan developed by USDA. These plans will promote consistency in regulations governing the legal production of hemp across the U.S.

In developing the sampling procedures for the Federal Plan, AMS considered the

protocols for sampling used by State departments of agriculture and by countries that regulate hemp production. In addition, AMS reviewed sampling methods recommended by Codex Alimentarius, which is the central part of the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Food Standards Program and was established by FAO and WHO to protect consumer health and promote fair practices in food trade. After research and review of multiple sampling protocols, AMS adopted the best option among the alternatives.

The 2018 Farm Bill mandates testing using post-decarboxylation or other similarly reliable methods where the total THC concentration level considers the potential to convert delta-9-tetrahydrocannabinolic *acid* (THC-A) into THC. Testing methodologies meeting these requirements include those using gas or liquid chromatography with detection. These methods are the industry standard for post-decarboxylation testing. While these methods were chosen by AMS as the best option for testing, alternative sampling and testing protocols will be considered if they are comparable to the baseline mandated by the 2018 Farm Bill and established under the USDA Plan and Procedures.

Alternatives to the selected procedures for sampling and testing for THC content included connecting a producer lot of cultivated hemp to a standard unit of measure. AMS considered describing one lot as one acre of hemp. This alternative was abandoned, however, as it would have required every acre of hemp to be sampled and tested, which would have resulted in high costs to producers and overwhelming volume to laboratories.

Good Cause Analysis

Pursuant to the Administrative Procedure Act (APA), notice and comment are not required prior to the issuance of a final rule if an agency, for good cause, finds that “notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” (5 U.S.C. 553(b)(B)).

USDA recognizes that courts have held that the good cause exception to notice and comment rulemaking is to be narrowly construed and only reluctantly countenanced. USDA does not take lightly its decision to forego a formal notice and comment process, but under a totality of the circumstances analysis, has concluded that this interim final rule (IFR), accompanied by a 60-day comment period, best balances Congress’s interest in the expeditious implementation of a regulatory program for domestic hemp production with its longstanding interest in ensuring that an agency’s decisions be informed and responsive. The IFR will also provide sorely needed guidance to the many stakeholders whose coordinated efforts are critical to the success of the domestic hemp production economy, and will serve the public’s interest by expediting hemp entry into that market.

Congress’s intention that USDA expeditiously develop a regulatory program for domestic hemp production is clear from language in the Agriculture Improvement Act of 2018, Public Law 115-334 (2018 Farm Bill), which the President signed into law on December 20, 2018. The 2018 Farm Bill amended the Agricultural Marketing Act of 1946 (Act) (7 U.S.C. 1621 et seq.) by adding subtitle G, Hemp Production. Upon enactment of the 2018 Farm Bill, hemp, as defined therein, is no longer a controlled substance. Section 10114 of the 2018 Farm Bill further clarifies that the interstate commerce of hemp is not prohibited, and that States and Indian Tribes cannot prohibit the transportation or shipment of hemp or hemp products produced in accordance

with the Agricultural Marketing Act of 1946 through the State or territory of the Indian Tribe. However, the Act also states that it is unlawful to produce hemp unless produced pursuant to a State, Tribal, or USDA plan. *See* 7 U.S.C. 1639p(a)(1) and 1639q(c)(1). Congress provided that the Secretary approve or disapprove of any State or Tribal plan within 60 days of its submission. 7 U.S.C. 1639(p)(b).

In order to meet this 60-day approval deadline, Congress understood that USDA would need time to establish its own plan and develop a process for quickly (i.e., within 60 days of submission) approving or disapproving of State and Tribal plans. Although the Act does not contain an express end-date by which such regulations and guidelines must be issued, in section 10113 of the 2018 Farm Bill, Congress provided that “[t]he Secretary shall promulgate regulations and guidelines to implement this subtitle as *expeditiously as practicable*.” (emphasis added). “To ensure that the Secretary moved forward with issuing regulations in as timely a fashion as possible,” the Act requires the Secretary to “periodically report to Congress with updates regarding implementation of this title.” H.R. Rep. 115-1072, at 738 (Dec. 10, 2018)(Conf. Rep.).

USDA takes seriously Congress’s directive to issue regulations as expeditiously as practicable. USDA also understands that while Congress did not expect USDA to issue regulations within 60 days, it also did not anticipate the process extending two years into 2021. This is apparent from Congress’s continued legislation on hemp. In Section 107 of the Additional Supplemental Appropriations for Disaster Relief Act, 2019, PL 116-20, (Disaster Relief Act), Congress required: “Beginning not later than the 2020 reinsurance year, the Federal Crop Insurance Corporation [FCIC] shall offer coverage under the whole farm revenue

protection insurance policy (or a successor policy or plan of insurance) for hemp (as defined in section 297A of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639o)).” Congress anticipated that regulations governing the interstate commerce of hemp would be issued prior to 2020; otherwise, the deadline in Section 107 of the Disaster Relief Act would be irrelevant. Additionally, several Members of Congress and Senators urged USDA to expedite the rulemaking or take steps to allow farmers to begin hemp production in 2019.

Despite USDA’s diligence, the complexity of establishing a new regulatory program for domestic hemp production, a crop that could not be legally grown on a commercial basis under Federal law for several decades, has taken a substantial amount of time and resources. Adding a formal notice and comment period on top of that would push the effective date of USDA’s domestic hemp production regulatory program well beyond 2020 and into 2021. This IFR effectuates Congress’s will, which is one of several factors that provide good cause to justify foregoing a notice and comment period.

A second factor justifying good cause is that this rule not only affects AMS’s ability to implement the congressionally mandated regulatory framework for a domestic program, but also provides critical guidance to numerous stakeholders that anxiously await the publication of this IFR. The FCIC’s insurance policy program discussed above is just one of these. For FCIC to offer the whole farm revenue protection insurance policy in 2020 to lawful producers of hemp under the Act, the IFR must take effect this fall to provide the Risk Management Agency (RMA) sufficient time to take the necessary steps to authorize FCIC to offer the insurance coverage and for producers to engage in activities to qualify for the coverage for their hemp production.

In addition, the FSA, the Rural Business-Cooperative Service, and the Natural Resources and Conservation Service provide financial incentives and support used by agricultural producers and private sector entities. These agencies similarly need regulatory guidance to develop commercial instruments such as loan documents, re-insurance contracts, and commodity disaster program provisions that are typically done on a crop year basis.

Individuals and commercial entities also need the IFR's guidance to engage in the production, harvesting, transportation, storage, and processing of hemp and hemp products. Absent an interim rule promptly implementing the regulatory program required by the 2018 Farm Bill, there are no procedures in place to determine whether a cannabis crop qualifies as hemp as defined in section 297A of the Agricultural Marketing Act of 1946. It is necessary to issue the IFR now to provide individuals and entities sufficient time to make the required plans and purchases and to obtain financing ahead of planting hemp in 2020.

The banking industry is awaiting these regulations in order to develop guidance regarding deposits derived from hemp operations. Without these regulations, the banking industry is not willing to take the risk of accepting deposits or lending money to these businesses. Additionally, with the IFR effective this fall, producers will be able to plan and execute the steps necessary to plant during the 2020 crop year. Those steps include identifying the land and acreage for the planting, contract for seed and other supplies, obtain financing, and identify and contract with potential buyers. Those steps are also necessary for producers to qualify for the USDA programs and products described above.

Finally, and importantly, law enforcement needs guidance from the IFR. While the States and Tribes may not prohibit the transportation of hemp produced under the 2014 Farm

Bill, law enforcement does not currently have the means to quickly verify whether the cannabis being transported is hemp or marijuana. The IFR will assist law enforcement in identifying lawfully-produced hemp versus other forms of cannabis that may not be lawfully transported in interstate commerce.

Adding a formal notice and comment period would push the effective date of USDA's regulatory program well beyond 2020 and into 2021 and delay the guidance these stakeholders sorely need.

A third factor justifying good cause for this rule is that the Administrator has solicited comments through listening sessions and webinar that solicited the public participation and consultations with State and Tribal officials.¹⁸ He is also allowing for a 60-day comment period for this IFR. The Administrator recognizes the value of public comment to refine the IFR and will keep an open mind as to any and all comment submissions. All written comments timely received will be considered before a final determination is made on this matter.

Finally, a fourth factor justifying good cause for the IFR is the public's interest in expediting the ability of the nation's farmers to enter the new agricultural market presented by hemp. As explained in the regulatory impact analysis above, USDA estimates that the industry should gain annualized benefits of almost \$66 million once the rule becomes effective and the domestic hemp production program is implemented. Any delay in the issuing regulations will cause producers to forgo realizing those benefits in 2020. In fact, earlier this year, USDA faced

¹⁸ For example, public comments from the March 19, 2019 webinar can be found at <https://www.ams.usda.gov/rules-regulations/farmbill-hemp/webinar-comments>.

litigation from a party who believed that the language in 7 U.S.C. 1639(p)(b) required USDA to approve State and tribal plans submitted to it in 60 days as soon as the law went into effect. *See Flandreau Santee Sioux Tribe v. United States Dep't of Agriculture et al.*, 4:19-cv-04094-KES (D.S.D.). The end of the spring planting season temporarily lowered the urgency felt by farmers seeking to enter the hemp market, but fall preparations for spring 2020's planting season are fast approaching. USDA has no doubt that it will again be subject to litigation if the IFR is not adopted in time for parties to prepare for the 2020 spring planting season.

Accordingly, the Administrator finds that, under the totality of the circumstances presented, there is good cause to forego notice and comment through the issuance of a notice of proposed rulemaking. By publishing this rule and making it effective this fall, USDA is complying with Congress's will, providing sorely needed guidance to all stakeholders, permitting public comment, and serving the public's interest in engaging in a new and promising economic endeavor. For similar reasons, the Administrator also finds good cause for the IFR to be effective upon publication in the Federal Register.

List of Subjects in 7 CFR Part 990

Acceptable hemp THC level, Agricultural commodities, Cannabis, Corrective action plan, Delta-9 tetrahydrocannabinol, Drugs, Dry weight basis, Hemp, High-performance liquid chromatography, Laboratories, Marijuana.

For the reasons set forth in the preamble, and under authority of 7 U.S.C. 601-674 and Public Law 107-171, add 7 CFR part 990 to read as follows:

PART 990—DOMESTIC HEMP PRODUCTION PROGRAM

Subpart A—Definitions

Sec.

990.1 Meaning of terms.

Subpart B—State and Tribal Hemp Production Plans

990.2 State and Tribal plans; General authority.

990.3 State and Tribal plans; Plan requirements.

990.4 USDA approval of State and Tribal plans.

990.5 Audit of State or Tribal plan compliance.

990.6 Violations of State and Tribal plans.

990.7 Establishing records with USDA Farm Service Agency.

990.8 Production under Federal law.

Subpart C—USDA Hemp Production Plan

990.20 USDA requirements for the production of hemp.

990.21 USDA hemp producer license.

990.22 USDA hemp producer license approval.

990.23 Reporting hemp crop acreage with USDA Farm Service Agency.

990.24 Responsibility of a USDA licensed producer prior to harvest.

990.25 Standards of performance for detecting delta-9 tetrahydrocannabinol (THC)
concentration levels.

990.26 Responsibility of a USDA producer after laboratory testing is performed.

990.27 Non-compliant cannabis plants.

990.28 Compliance.

990.29 Violations.

990.30 USDA producers; License suspension.

990.31 USDA licensees; Revocation.

990.32 Recordkeeping requirements.

Subpart D—Appeals

990.40 General adverse action appeal process.

990.41 Appeals under the USDA hemp production plan.

990.42 Appeals under a State or Tribal hemp production plan.

Subpart E—Administrative Provisions

990.60 Agents.

990.61 Severability.

990.62 Expiration of this part.

990.63 Interstate transportation of hemp.

Subpart F—Reporting Requirements

990.70 State and Tribal hemp reporting requirements.

990.71 USDA plan reporting requirements.

Authority: 7 U.S.C. 1639o note, 1639p, 1639q, and 1639r.

Subpart A—Definitions

§990.1 Meaning of terms.

Words used in this subpart in the singular form shall be deemed to impart the plural, and vice versa, as the case may demand. For the purposes of provisions and regulations of this part, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

Acceptable hemp THC level. When a laboratory tests a sample, it must report the delta-9 tetrahydrocannabinol content concentration level on a dry weight basis and the measurement of uncertainty. The acceptable hemp THC level for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans is when the application of the measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution or range that includes 0.3% or less. For example, if the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis is 0.35% and the measurement of uncertainty is +/- 0.06%, the measured delta-9 tetrahydrocannabinol content concentration level on a dry weight basis for this sample ranges from 0.29% to 0.41%. Because 0.3% is within the distribution or range, the sample is within the acceptable hemp THC level for the purpose of plan compliance. This definition of “acceptable hemp THC level” affects neither the statutory definition of hemp, 7 U.S.C. 1639o (1), in the 2018 Farm Bill nor the definition of “marihuana,” 21 U.S.C. 802(16), in the CSA.

Act. Agricultural Marketing Act of 1946.

Agricultural Marketing Service or *AMS.* The Agricultural Marketing Service of the U.S. Department of Agriculture.

Applicant. An applicant is:

- (1) A State or Indian Tribe that has submitted a State or Tribal hemp production plan to USDA for approval under this part; or
- (2) A producer in a State or territory of an Indian Tribe who is not subject to a State or Tribal hemp production plan and who has submitted an application for a license under the USDA hemp production plan under this part.

Cannabis. A genus of flowering plants in the family Cannabaceae of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. Cannabis refers to any form of the plant in which the delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined.

Controlled Substances Act (CSA). The Controlled Substances Act as codified in 21 U.S.C. 801 *et seq.*

Conviction. Means any plea of guilty or nolo contendere, or any finding of guilt, except when the finding of guilt is subsequently overturned on appeal, pardoned, or expunged. For purposes of this part, a conviction is expunged when the conviction is removed from the individual's criminal history record and there are no legal disabilities or restrictions associated with the expunged conviction, other than the fact that the conviction may be used for sentencing purposes for subsequent convictions. In addition, where an individual is allowed to withdraw an original plea of guilty or nolo contendere and enter a plea of not guilty and the case is subsequently dismissed, the individual is no longer considered to have a conviction for purposes of this part.

Corrective action plan. A plan established by a State, Tribal government, or USDA for a licensed hemp producer to correct a negligent violation or non-compliance with a hemp production plan and this part.

Criminal History Report. Criminal history report means the Federal Bureau of Investigation's Identity History Summary.

Culpable mental state greater than negligence. To act intentionally, knowingly, willfully, or recklessly.

Decarboxylated. The completion of the chemical reaction that converts THC-acid (THC-A) into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of THC-acid.

Decarboxylation. The removal or elimination of carboxyl group from a molecule or organic compound.

Delta-9 tetrahydrocannabinol or THC. Delta-9 THC is the primary psychoactive component of cannabis. For the purposes of this part, delta-9 THC and THC are interchangeable.

Drug Enforcement Administration or DEA. The United States Drug Enforcement Administration.

Dry weight basis. The ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

Entity. A corporation, joint stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization, including any such organization participating in the hemp production as a partner in a general partnership, a participant in a joint venture, or a participant in a similar organization.

Farm Service Agency or FSA. An agency of the United States Department of Agriculture.

Gas chromatography or *GC*. A type of chromatography in analytical chemistry used to separate, identify, and quantify each component in a mixture. GC relies on heat for separating and analyzing compounds that can be vaporized without decomposition.

Geospatial location. For the purposes of this part, “geospatial location” means a location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

Handle. To harvest or store hemp plants or hemp plant parts prior to the delivery of such plants or plant parts for further processing. “Handle” also includes the disposal of cannabis plants that are not hemp for purposes of chemical analysis and disposal of such plants.

Hemp. The plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

High-performance liquid chromatography or *HPLC*. A type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. HPLC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds.

Indian Tribe. As defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

Information sharing system. The database mandated under the Act which allows USDA to share information collected under State, Tribal, and USDA plans with Federal, State, Tribal,

and local law enforcement.

Key participants. A sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer and chief financial officer. This definition does not include non-executive managers such as farm, field, or shift managers.

Law enforcement agency. Any Federal, State, or local law enforcement agency.

Lot. A contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout the area.

Marijuana. As defined in the CSA, “marihuana” means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. The term ‘marihuana’ does not include hemp, as defined in section 297A of the Agricultural Marketing Act of 1946, and does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (7 U.S.C. 1639o). “Marihuana” means all cannabis that tests as having a concentration level of THC on a dry weight basis of higher than 0.3 percent.

Measurement of Uncertainty (MU). The parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

Negligence. Failure to exercise the level of care that a reasonably prudent person would

exercise in complying with the regulations set forth under this part.

Phytocannabinoid. Cannabinoid chemical compounds found in the cannabis plant, two of which are Delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD).

Plan. A set of criteria or regulations under which a State or Tribal government, or USDA, monitors and regulates the production of hemp.

Postdecarboxylation. In the context of testing methodologies for THC concentration levels in hemp, means a value determined after the process of decarboxylation that determines the total potential delta-9 tetrahydrocannabinol content derived from the sum of the THC and THC-A content and reported on a dry weight basis. The postdecarboxylation value of THC can be calculated by using a chromatograph technique using heat, gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The postdecarboxylation value of THC can also be calculated by using a high-performance liquid chromatograph technique, which keeps the THC-A intact, and requires a conversion calculation of that THC-A to calculate total potential THC in a given sample. See the definition for decarboxylation.

Produce. To grow hemp plants for market, or for cultivation for market, in the United States.

Producer. Producer means a producer as defined in 7 CFR 718.2 that is licensed or authorized to produce hemp under this part.

Reverse distributor. A person who is registered with the DEA in accordance with 21 CFR 1317.15 to dispose of marijuana under the Controlled Substances Act.

Secretary. The Secretary of Agriculture of the United States.

State. Any one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

State department of agriculture. The agency, commission, or department of a State government responsible for agriculture in the State.

Territory of the Indian Tribe has the same meaning as “Indian Country” in 18 U.S.C. 1151.

Tribal government. The governing body of an Indian Tribe.

USDA licensed hemp producer or licensee. A person, partnership, or corporation authorized by USDA to produce hemp.

Subpart B—State and Tribal Hemp Production Plans

§990.2 State and Tribal plans; General authority.

States or Indian Tribes desiring to have primary regulatory authority over the production of hemp in the State or territory of the Indian Tribe for which it has jurisdiction shall submit to the Secretary for approval, through the State department of agriculture (in consultation with the Governor and chief law enforcement officer of the State) or the Tribal government, as applicable, a plan under which the State or Indian Tribe monitors and regulates that production.

§990.3 State and Tribal plans; Plan requirements.

(a) *General requirements.* A State or Tribal plan submitted to the Secretary for approval must include the practice and procedures described in this paragraph (a).

(1) A State or Tribal plan must include a practice to collect, maintain, and report to the Secretary relevant, real-time information for each producer licensed or authorized to produce hemp under the State or Tribal plan regarding:

(i) Contact information as described in § 990.70(a)(1);

(ii) A legal description of the land on which the producer will produce hemp in the State or territory of the Indian Tribe including, to the extent practicable, its geospatial location; and

(iii) The status and number of the producer's license or authorization.

(2) A State or Tribal plan must include a procedure for accurate and effective sampling of all hemp produced, to include the requirements in this paragraph (a)(2).

(i) Within 15 days prior to the anticipated harvest of cannabis plants, a Federal, State, local, or Tribal law enforcement agency or other Federal, State, or Tribal designated person shall collect samples from the flower material from such cannabis plants for delta-9 tetrahydrocannabinol concentration level testing as described in §§ 990.24 and 990.25.

(ii) The method used for sampling from the flower material of the cannabis plant must be sufficient at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.

(iii) During a scheduled sample collection, the producer or an authorized representative of the producer shall be present at the growing site.

(iv) Representatives of the sampling agency shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants, whether growing or harvested, and all land, buildings, and other structures used for the cultivation, handling, and

storage of all hemp and other cannabis plants, and all locations listed in the producer license.

(v) A producer shall not harvest the cannabis crop prior to samples being taken.

(3) A State or Tribal plan must include a procedure for testing that is able to accurately identify whether the sample contains a delta-9 tetrahydrocannabinol content concentration level that exceeds the acceptable hemp THC level. The procedure must include a validated testing methodology that uses postdecarboxylation or other similarly reliable methods. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic *acid* (THC-A) in hemp into THC and the test result measures total available THC derived from the sum of the THC and THC-A content. Testing methodologies meeting the requirements of this paragraph (a)(3) include, but are not limited to, gas or liquid chromatography with detection. The total THC concentration level shall be determined and reported on a dry weight basis.

(i) Any test of a representative sample resulting in higher than the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part. Lots tested and not certified by the DEA-registered laboratory at or below the acceptable hemp THC level may *not* be further handled, processed or enter the stream of commerce and the producer shall ensure the lot is disposed of in accordance with § 990.27.

(ii) Samples of hemp plant material from one lot shall not be commingled with hemp plant material from other lots.

(iii) Analytical testing for purposes of detecting the concentration levels of THC shall meet the following standards:

(A) Laboratory quality assurance must ensure the validity and reliability of test results;

(B) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose), and that the laboratory can successfully perform the testing;

(C) The demonstration of testing validity must ensure consistent, accurate analytical performance;

(D) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part; and

(E) An effective disposal procedure for hemp plants that are produced that do not meet the requirements of this part. The procedure must be in accordance with DEA reverse distributor regulations found at 21 CFR 1317.15.

(F) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(4) A State or Indian Tribe shall promptly notify the Administrator by certified mail or electronically of any occurrence of cannabis plants or plant material that do not meet the definition of hemp in this part and attach the records demonstrating the appropriate disposal of all of those plants and materials in the lot from which the representative samples were taken.

(5) A State or Tribal plan must include a procedure to comply with the enforcement procedures in §990.6.

(6) A State or Tribal plan must include a procedure for conducting annual inspections of, at a minimum, a random sample of producers to verify that hemp is not produced in violation of

this part. These procedures must enforce the terms of violations as stated in the Act and defined under §990.6.

(7) A State or Tribal plan must include a procedure for submitting the information described in § 990.70 to the Secretary not more than 30 days after the date on which the information is received. All such information must be submitted to the USDA in a format that is compatible with USDA's information sharing system.

(8) The State or Tribal government must certify that the State or Indian Tribe has the resources and personnel to carry out the practices and procedures described in paragraphs (a)(1) through (7) of this section.

(9) The State or Tribal plan must include a procedure to share information with USDA to support the information sharing requirements in 7 U.S.C. 1639q(d). The procedure must include the requirements described in this paragraph (a)(9).

(i) The State or Tribal plan shall require producers to report their hemp crop acreage to the FSA, consistent with the requirement in § 990.7.

(ii) The State or Tribal government shall assign each producer with a license or authorization identifier in a format prescribed by USDA.

(iii) The State or Tribal government shall require producers to report the total acreage of hemp planted, harvested, and, if applicable, disposed. The State or Tribal government shall collect this information and report it to AMS.

(b) *Relation to State and Tribal law.* A State or Tribal plan may include any other practice or procedure established by a State or Indian Tribe, as applicable; *Provided,* That the practice or procedure is consistent with this part and Subtitle G of the Act.

(1) *No preemption.* Nothing in this part preempts or limits any law of a State or Indian Tribe that:

- (i) Regulates the production of hemp; and
- (ii) Is more stringent than this part or Subtitle G of the Act.

(2) *References in plans.* A State or Tribal plan may include a reference to a law of the State or Indian Tribe regulating the production of hemp, to the extent that the law is consistent with this part.

§990.4 USDA approval of State and Tribal plans.

(a) *General authority.* No plans will be accepted by USDA prior to [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. No later than 60 calendar days after the receipt of a State or Tribal plan for a State or Tribal Nation in which production of hemp is legal, the Secretary shall:

(1) Approve the State or Tribal plan only if the State or Tribal plan complies with this part; or

(2) Disapprove the State or Tribal plan if the State or Tribal plan does not comply with this part. USDA shall provide written notification to the State or Tribe of the disapproval and the cause for the disapproval.

(b) *Amended plans.* A State or Tribal government, as applicable, must submit to the Secretary an amended plan if:

(1) The Secretary disapproves a State or Tribal plan if the State or Tribe wishes to have primary jurisdiction over hemp production within its State or territory of the Indian Tribe; or

(2) The State or Tribe makes substantive revisions to its plan or its laws which alter the

way the plan meets the requirements of this part. If this occurs, the State or Tribal government must re-submit the plan with any modifications based on laws and regulation changes for USDA approval. Such re-submissions should be provided to USDA within 365 days from the date that the State or Tribal laws and regulations are effective. Producers shall continue to comply with the requirements of the existing plan while such modifications are under consideration by USDA. If State or Tribal government laws or regulations in effect under the USDA-approved plan change but the State or Tribal government does not re-submit a modified plan within one year from the effective date of the new law or regulation, the existing plan is revoked.

(3) USDA approval of State or Tribal government plans shall remain in effect unless an amended plan must be submitted to USDA because of a substantive revision to a State's or Tribe's plan, a relevant change in State or Tribal laws or regulations, or approval of the plan is revoked by USDA.

(c) *Technical assistance.* The Secretary may provide technical assistance to help a State or Indian Tribe develop or amend a plan. This may include the review of draft plans or other informal consultation as necessary.

(d) *Approved State or Tribal plans.* If the Secretary approves a State or Tribal plan, the Secretary shall notify the State or Tribe by letter or email.

(1) In addition to the approval letter, the State or Tribe shall receive their plan approval certificate either as an attachment or assessable via website link.

(2) The USDA shall post information regarding approved plans on its website.

(3) USDA approval of State or Tribal government plans shall remain in effect unless:

(i) The State or Tribal government laws and regulations in effect under the USDA-

approved plan change, thus requiring such plan to be re-submitted for USDA approval.

(ii) A State or Tribal plan must be amended in order to comply with amendments to Subtitle G the Act and this part.

(e) *Producer rights upon revocation of State or Tribal plan.* If USDA revokes approval of the State or Tribal plan due to noncompliance as defined in §990.5, producers licensed or authorized to produce hemp under the revoked State or Tribal plan may continue to produce for the remainder of the calendar year in which the revocation became effective. Producers may then apply to be licensed under the USDA plan for 90 days after the notification even if the time period does not coincide with the annual application window.

§990.5 Audit of State or Tribal plan compliance.

The Secretary may conduct an audit of the compliance of a State or Indian Tribe with an approved plan.

(a) *Frequency of audits.* Compliance audits may be scheduled, at minimum, once every three years and may include an onsite-visit, a desk-audit, or both. The USDA may adjust the frequency of audits if deemed appropriate based on program performance, compliance issues, or other relevant factors identified and provided to the State or Tribal governments by USDA.

(b) *Scope of audit review.* The audit may include, but is not limited to, a review of the following:

- (1) The resources and personnel employed to administer and oversee its approved plan;
- (2) The process for licensing and systematic compliance review of hemp producers;
- (3) Sampling methods and laboratory testing requirements and components;
- (4) Disposal of non-compliant hemp plants or hemp plant material practices, to ensure

that correct reporting to the USDA has occurred;

(5) Results of and methodology used for the annual inspections of producers; and

(6) Information collection procedures and information accuracy (*i.e.*, geospatial location, contact information reported to the USDA, legal description of land).

(c) *Audit reports.* (1) Audit reports will be issued to the State or Tribal government within 60 days after the audit concluded. If the audit reveals that the State or Tribal government is not in compliance with its USDA approved plan, USDA will advise the State or Indian Tribe of non-compliances and the corrective measures that must be completed to come into compliance with the regulations in this part. The USDA will require the State or Tribe to develop a corrective action plan, which will be reviewed and approved by the USDA, and the State or Tribe will be able to demonstrate its compliance with the regulations in this part through a second audit by USDA. If the State or Tribe requests USDA assistance to develop a corrective action plan in the case of a first instance of noncompliance, the State or Tribe must request this assistance not later than 30 days after the issuance of the audit report. The USDA will approve or deny the corrective action plan within 60 days of its receipt.

(2) If the USDA determines that the State or Indian Tribe is not in compliance after the second audit, the USDA may revoke its approval of the State or Tribal plan for a period not to exceed one year. USDA will not approve a State or Indian Tribe's plan until the State or Indian Tribe demonstrates upon inspection that it is in compliance with all regulations in this part.

§990.6 Violations of State and Tribal plans.

(a) *Producer violations.* Producer violations of USDA-approved State and Tribal hemp production plans shall be subject to enforcement in accordance with the terms of this section.

(b) *Negligent violations.* Each USDA-approved State or Tribal plan shall contain provisions relating to negligent producer violations as defined under this part. Negligent violations shall include, but not be limited to:

- (1) Failure to provide a legal description of land on which the producer produces hemp;
- (2) Failure to obtain a license or other required authorization from the State department of agriculture or Tribal government, as applicable; or
- (3) Production of cannabis with a delta-9 tetrahydrocannabinol concentration exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation under this paragraph (b)(3) if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a delta-9 tetrahydrocannabinol concentration of more than 0.5 percent on a dry weight basis.

(c) *Corrective action for negligent violations.* Each USDA-approved State or Tribal plan shall contain rules and regulations providing for the correction of negligent violations. Each correction action plan shall include, at minimum, the following terms:

- (1) A reasonable date by which the producer shall correct the negligent violation.
- (2) A requirement that the producer shall periodically report to the State department of agriculture or Tribal government, as applicable, on its compliance with the State or Tribal plan for a period of not less than the next 2 years from the date of the negligent violation.
- (3) A producer that negligently violates a State or Tribal plan approved under this part shall not as a result of that violation be subject to any criminal enforcement action by the Federal, State, Tribal, or local government.

(4) A producer that negligently violates a USDA-approved State or Tribal plan three times in a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(5) The State or Tribe shall conduct an inspection to determine if the corrective action plan has been implemented as submitted.

(d) *Culpable violations.* Each USDA-approved State or Tribal plan shall contain provisions relating to producer violations made with a culpable mental state greater than negligence, including that:

(1) If the State department of agriculture or Tribal government with an approved plan determines that a producer has violated the plan with a culpable mental state greater than negligence, the State department of agriculture or Tribal government, as applicable, shall immediately report the producer to:

(i) The U.S. Attorney General; and

(ii) The chief law enforcement officer of the State or Indian Tribe, as applicable.

(2) Paragraphs (b) and (c) of this section shall not apply to culpable violations.

(e) *Felonies.* Each USDA-approved State or Tribal plan shall contain provisions relating to felonies. Such provisions shall state that:

(1) A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on participating in the plan and producing hemp under the State or Tribal plan from the date of the conviction. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

(2) Any producer growing hemp lawfully with a license, registration, or authorization under a pilot program authorized by section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] shall be exempted from paragraph (e)(1) of this section.

(3) For producers that are entities, the State or Tribal plan shall determine which employee(s) of a producer shall be considered to be participating in the plan and subject to the felony conviction restriction for purposes of paragraph (e)(1) of this section.

(f) *False statement.* Each USDA-approved State or Tribal plan shall state that any person who materially falsifies any information contained in an application to participate in such program shall be ineligible to participate in that program.

(g) *Appeals.* For States and Tribes who wish to appeal an adverse action, subpart D of this part will apply.

§990.7 Establishing records with USDA Farm Service Agency.

All producers licensed to produce hemp under an USDA-approved State or Tribal plan shall report hemp crop acreage with FSA and shall provide, at minimum, the following information:

(a) Street address and, to the extent practicable, geospatial location for each lot or greenhouse where hemp will be produced. If an applicant operates in more than one location, that information shall be provided for all production sites.

(b) If an applicant has production sites licensed under a USDA-approved State or Tribal plan, those sites will be covered under the respective plan and will not need to be included under the producer's application to become licensed under the USDA plan.

(c) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(d) License or authorization identifier.

§990.8 Production under Federal law.

Nothing in this subpart prohibits the production of hemp in a State or the territory of an Indian Tribe for which a State or Tribal plan is not approved under this subpart if the production of that hemp is in accordance with subpart C of this part, and if the production of hemp is not otherwise prohibited by the State or Indian Tribe.

Subpart C—USDA Hemp Production Plan

§990.20 USDA requirements for the production of hemp.

(a) *General hemp production requirements.* The production of hemp in a State or territory of an Indian Tribe where there is no USDA approved State or Tribal plan must be produced in accordance with this subpart provided that the production of hemp is not prohibited by the State or territory of an Indian Tribe where production will occur.

(b) *Convicted felon ban.* A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on participating in the plan and producing hemp under the USDA plan from the date of the conviction. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before December 20, 2018.

(c) *Falsifying material information on application.* Any person who materially falsifies any information contained in an application to for a license under the USDA plan shall be ineligible to participate in the USDA plan.

§990.21 USDA hemp producer license.

(a) *General application requirements--(1) Requirements and license application.* Any person producing or intending to produce hemp must have a valid license prior to producing, cultivating, or storing hemp. A valid license means the license is unexpired, unsuspended, and unrevoked.

(2) *Application window.* Applicants may submit an application for a new license to USDA between [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and November 2, 2020. In subsequent years, applicants may submit an application for a new license or renewal of an existing license to USDA from August 1 through October 31 of each year.

(3) *Required information on application.* The applicant shall provide the information requested on the application form, including:

(i) *Contact information.* Full name, residential address, telephone number and email address. If the applicant is a business entity, the full name of the business, the principal business location address, full name and title of the key participants, title, email address (if available) and employer identification number (EIN) of the business; and

(ii) *Criminal history report.* A current criminal history report for all key participants dated within 60 days prior to the application submission date. A license application will not be considered complete without all required criminal history reports.

(4) *Submission of completed application forms.* Completed application forms shall be submitted to USDA.

(5) *Incomplete application procedures.* Applications missing required information shall be returned to the applicant as incomplete. The applicant may resubmit a completed application.

(6) *License expiration.* USDA-issued hemp producer licenses shall be valid until December 31 of the year three years after the year in which license was issued.

(b) *License renewals.* USDA hemp producer licenses must be renewed prior to license expiration. Licenses are not automatically renewed. Applications for renewal shall be subject to the same terms, information collection requirements, and approval criteria as provided in this subpart for initial applications unless there has been an amendment to the regulations in this part or the law since approval of the initial or last application.

(c) *License modification.* A license modification is required if there is any change to the information submitted in the application including, but not limited to, sale of a business, the production, handling, or storage of hemp in a new location, or a change in the key participants producing under a license.

§990.22 USDA Hemp producer license approval.

(a) A license shall not be issued unless:

(1) The application submitted for USDA review and approval is complete and accurate.

(2) The criminal history report(s) submitted with the license application confirms that all key participants to be covered by the license have not been convicted of a felony, under State or Federal law, relating to a controlled substance within the past ten (10) years unless the exception in §990.20(b) applies.

(3) The applicant has submitted all reports required as a participant in the hemp production program by this part.

(4) The application contains no materially false statements or misrepresentations and the applicant has not previously submitted an application with any materially false statements or misrepresentations.

(5) The applicant's license is not currently suspended.

(6) The applicant is not applying for a license as a stand-in for someone whose license has been suspended, revoked, or is otherwise ineligible to participate.

(7) The State or territory of Indian Tribe where the person produces or intends to produce hemp does not have a USDA-approved plan or has not submitted a plan to USDA for approval and is awaiting USDA's decision. For the first year, USDA will not accept request for licenses under the USDA plan until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to allow States and Tribes to submit their plans.

(8) The State or territory of Indian Tribe where the person produces or intends to produce hemp does not prohibit the production of hemp.

(b) USDA shall provide written notification to applicants whether the application has been approved or denied unless the applicant is from a State or territory of an Indian Tribe that has a plan submitted to USDA and is awaiting USDA approval.

(1) If an application is approved, a license will be issued. Information regarding approved licenses will be available on the AMS website.

(2) Licenses will be valid until December 31 of the year three after the year in which the license was issued.

(3) Licenses may not be sold, assigned, transferred, pledged, or otherwise disposed of, alienated or encumbered.

(4) If a license application is denied, the notification from USDA will explain the cause for denial. Applicants may appeal the denial in accordance with subpart D of this part.

(c) If the applicant is producing in more than one location, the applicant may have more than one license to grow hemp. If the applicant has operations in a location covered under a State or Tribal plan, that operation must be licensed under the State or Tribal plan, not a USDA plan.

§990.23 Reporting hemp crop acreage with USDA Farm Service Agency.

All USDA plan producers shall report hemp crop acreage with FSA and shall provide, at minimum, the following information:

(a) Street address and, to the extent practicable, geospatial location of the lot, greenhouse, building, or site where hemp will be produced. All locations where hemp is produced must be reported to FSA.

(b) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(c) The license number.

§990.24 Responsibility of a USDA licensed producer prior to harvest.

(a) Within 15 days prior to the anticipated harvest of cannabis plants, a producer shall have an approved Federal, State, local law enforcement agency or other USDA designated person collect samples from the flower material of such cannabis material for delta-9 tetrahydrocannabinol concentration level testing.

(b) The method used for sampling from the flower material of the cannabis plant must be sufficient at a confidence level of 95 percent that no more than one percent (1%) of the plants in

the lot would exceed the acceptable hemp THC level. The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.

(c) During a scheduled sample collection, the producer or an authorized representative of the producer shall be present at the growing site.

(d) Representatives of the sampling agency shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants, whether growing or harvested, and all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

(e) A producer shall not harvest the cannabis crop prior to samples being taken.

§990.25 Standards of performance for detecting delta-9 tetrahydrocannabinol (THC) concentration levels.

(a) Analytical testing for purposes of detecting the concentration levels of delta-9 tetrahydrocannabinol (THC) in the flower material of the cannabis plant shall meet the following standard:

(1) Laboratory quality assurance must ensure the validity and reliability of test results;

(2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(3) The demonstration of testing validity must ensure consistent, accurate analytical performance; and

(4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

(b) At a minimum, analytical testing of samples for delta-9 tetrahydrocannabinol concentration levels must use post-decarboxylation or other similarly reliable methods approved by the Secretary. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) in hemp into delta-9 tetrahydrocannabinol (THC) and the test result reflect the total available THC derived from the sum of the THC and THC-A content. Testing methodologies meeting the requirements of this paragraph (b) include, but are not limited to, gas or liquid chromatography with detection.

(c) The total delta-9 tetrahydrocannabinol concentration level shall be determined and reported on a dry weight basis. Additionally, measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(d) Any sample test result exceeding the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part.

§990.26 Responsibility of a USDA producer after laboratory testing is performed.

(a) The producer shall harvest the crop not more than fifteen (15) days following the date of sample collection.

(b) If the producer fails to complete harvest within fifteen (15) days of sample collection, a secondary pre-harvested sample of the lot shall be required to be submitted for testing.

(c) Harvested lots of hemp plants shall not be commingled with other harvested lots or other material without prior written permission from USDA.

(d) Lots that meet the acceptable hemp THC level may enter the stream of commerce.

(e) Lots tested and *not* certified by the DEA-registered laboratory not exceeding the

acceptable hemp THC level may *not* be further handled, processed, or enter the stream of commerce and the licensee shall ensure the lot is disposed of in accordance with §990.27.

(f) Any producer may request additional testing if it is believed that the original delta-9 tetrahydrocannabinol concentration level test results were in error.

§990.27 Non-compliant cannabis plants.

(a) Cannabis plants exceeding the acceptable hemp THC level constitute marijuana, a schedule I controlled substance under the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, and must be disposed of in accordance with the CSA and DEA regulations found at 21 CFR 1317.15.

(b) Producers must notify USDA of their intent to dispose of non-conforming plants and verify disposal by submitting required documentation.

§990.28 Compliance.

(a) *Audits.* Producers may be audited by the USDA. The audit may include a review of records and documentation, and may include site visits to farms, fields, greenhouses, storage facilities, or other locations affiliated with the producer's hemp operation. The inspection may include the current crop year, as well as any previous crop year(s). The audit may be performed remotely or in person.

(b) *Frequency of audit verifications.* Audit verifications may be performed once every three (3) years unless otherwise determined by USDA. If the results of the audit find negligent violations, a corrective action plan may be established.

(c) *Assessment of producer's hemp operations for conformance.* The producer's operational procedures, documentation, and recordkeeping, and other practices may be verified

during the onsite audit verification. The auditor may also visit the production, cultivation, or storage areas for hemp listed on the producer's license.

(1) *Records and documentation.* The auditor shall assess whether required reports, records, and documentation are properly maintained for accuracy and completeness.

(2) [Reserved]

(d) *Audit reports.* Audit reports will be issued to the licensee within 60 days after the audit is concluded. If USDA determines under an audit that the producer is not compliant with this part, USDA shall require a corrective action plan. The producer's implementation of a corrective action plan may be reviewed by USDA during a future site visit or audit.

§990.29 Violations.

Violations of this part shall be subject to enforcement in accordance with the terms of this section.

(a) *Negligent violations.* A hemp producer shall be subject to enforcement for negligently:

(1) Failing to provide an accurate legal description of land where hemp is produced;

(2) Producing hemp without a license; and

(3) Producing cannabis (marijuana) exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation under this paragraph (a) if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a delta-9 tetrahydrocannabinol concentration of more than 0.5 percent on a dry weight basis.

(b) *Corrective action for negligent violations.* For each negligent violation, USDA will issue a Notice of Violation and require a corrective action plan for the producer. The producer

shall comply with the corrective action plan to cure the negligent violation. Corrective action plans will be in place for a minimum of two (2) years from the date of their approval. Corrective action plans will, at a minimum, include:

- (1) The date by which the producer shall correct each negligent violation;
- (2) Steps to correct each negligent violation; and
- (3) A description of the procedures to demonstrate compliance must be submitted to

USDA.

(c) *Negligent violations and criminal enforcement.* A producer that negligently violates this part shall not, as a result of that violation be subject to any criminal enforcement action by any Federal, State, Tribal, or local government.

(d) *Subsequent negligent violations.* If a subsequent violation occurs while a corrective action plan is in place, a new corrective action plan must be submitted with a heightened level of quality control, staff training, and quantifiable action measures.

(e) *Negligent violations and license revocation.* A producer that negligently violates the license 3 times in a 5-year period shall have their license revoked and be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(f) *Culpable mental state greater than negligence.* If USDA determines that a licensee has violated the terms of the license or of this part with a culpable mental state greater than negligence:

- (1) USDA shall immediately report the licensee to:
 - (i) The U.S. Attorney General; and

(ii) The chief law enforcement officer of the State or Indian territory, as applicable, where the production is located; and

(2) Paragraphs (a) and (b) of this section shall not apply to culpable violations.

§990.30 USDA producers; License suspension.

(a) USDA may issue a notice of suspension to a producer if USDA or its representative receives some credible evidence establishing that a producer has:

(1) Engaged in conduct violating a provision of this part; or

(2) Failed to comply with a written order from the USDA-AMS Administrator related to negligence as defined in this part.

(b) Any producer whose license has been suspended shall not handle or remove hemp or cannabis from the location where hemp or cannabis was located at the time when USDA issued its notice of suspension, without prior written authorization from USDA.

(c) Any person whose license has been suspended shall not produce hemp during the period of suspension.

(d) A producer whose license has been suspended may appeal that decision in accordance with subpart D of this part.

(e) A producer whose license has been suspended and not restored on appeal may have their license restored after a waiting period of one year from the date of the suspension.

(f) A producer whose license has been suspended may be required to complete a corrective action plan to fully restore the license.

§990.31 USDA licensees; Revocation.

USDA shall immediately revoke the license of a USDA producer if such producer:

- (a) Pleads guilty to, or is convicted of, any felony related to a controlled substance; or
- (b) Made any materially false statement with regard to this part to USDA or its representatives with a culpable mental state greater than negligence; or
- (c) Is found to be growing cannabis exceeding the acceptable hemp THC level with a culpable mental state greater than negligence or negligently violated this part three times in five years.

§990.32 Recordkeeping requirements.

- (a) USDA producers shall maintain records of all hemp plants acquired, produced, handled, or disposed of as will substantiate the required reports.
- (b) All records and reports shall be maintained for at least three years.
- (c) All records shall be made available for inspection by USDA inspectors, auditors, or their representatives during reasonable business hours. The following records must be made available:
 - (1) Records regarding acquisition of hemp plants;
 - (2) Records regarding production and handling of hemp plants;
 - (3) Records regarding storage of hemp plants; and
 - (4) Records regarding disposal of all cannabis plants that do not meet the definition of hemp.
- (d) USDA inspectors, auditors, or their representatives shall have access to any premises where hemp plants may be held during reasonable business hours.
- (e) All reports and records required to be submitted to USDA as part of participation in the program in this part which include confidential data or business information, including but

not limited to information constituting a trade secret or disclosing a trade position, financial condition, or business operations of the particular licensee or their customers, shall be received by, and at all times kept in the custody and control of, one or more employees of USDA or their representatives. Confidential data or business information may be shared with applicable Federal, State, Tribal, or local law enforcement or their designee in compliance with the Act.

Subpart D—Appeals

§ 990.40 General adverse action appeal process.

(a) Persons who believe they are adversely affected by the denial of a license application under the USDA hemp production program may appeal such decision to the AMS Administrator.

(b) Persons who believe they are adversely affected by the denial of a license renewal under the USDA hemp production program may appeal such decision to the AMS Administrator.

(c) Persons who believe they are adversely affected by the termination or suspension of a USDA hemp production license may appeal such decision to the AMS Administrator.

(d) States and territories of Indian Tribes that believe they are adversely affected by the denial of a proposed State or Tribal hemp plan may appeal such decision to the AMS Administrator.

§ 990.41 Appeals under the USDA hemp production plan.

(a) *Appealing a denied USDA-plan license application.* A license applicant may appeal the denial of a license application.

(1) If the AMS Administrator sustains an applicant's appeal of a licensing denial, the applicant will be issued a USDA hemp production license.

(2) If the AMS Administrator denies an appeal, the applicant's license application will be denied. The applicant may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(b) *Appealing a denied USDA-plan license renewal.* A producer may appeal the denial of a license renewal.

(1) If the AMS Administrator sustains a producer's appeal of a licensing renewal decision, the applicant's USDA hemp production license will be renewed.

(2) If the AMS Administrator denies the appeal, the applicant's license will not be renewed. The denied producer may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(c) *Appealing a USDA-plan license termination or suspension.* A USDA hemp plan producer may appeal the termination or suspension of a license.

(1) If the AMS Administrator sustains the appeal of a license termination or suspension, the producer will retain their license.

(2) If the AMS Administrator denies the appeal, the producer's license will be terminated or suspended. The producer may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(d) *Filing period.* The appeal of a denied license application, denied license renewal, suspension, or termination must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. The appeal will be considered “filed” on the date received by the AMS Administrator. The decision to deny a license application or renewal, or suspend or terminate a license, is final unless a formal adjudicatory proceeding is requested within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture’s Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(e) *Where to file.* Appeals to the Administrator must be filed in the manner as determined by AMS.

(f) *What to include.* All appeals must include a copy of the adverse decision and a statement of the appellant’s reasons for believing that the decision was not proper or made in accordance with applicable program regulations in this part, policies, or procedures.

§ 990.42 Appeals under a State or Tribal hemp production plan.

(a) *Appealing a State or Tribal hemp production plan application.* A State or Tribe may appeal the denial of a proposed State or Tribal hemp production plan by the USDA.

(1) If the AMS Administrator sustains a State or Tribe’s appeal of a denied hemp plan application, the proposed State or Tribal hemp production plan shall be established as proposed.

(2) If the AMS Administrator denies an appeal, the proposed State or Tribal hemp production plan shall not be approved. Prospective producers located in the State or territory of the Indian Tribe may apply for hemp licenses under the terms of the USDA plan. The State or Tribe may request a formal adjudicatory proceeding be initiated within 30 days to review the

decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(b) *Appealing the suspension or termination of a State or Tribal hemp production plan.* A State or Tribe may appeal the revocation by USDA of an existing State or Tribal hemp production plan.

(1) If the AMS Administrator sustains a State or Tribe's appeal of a State or Tribal hemp production plan suspension or revocation, the associated hemp production plan may continue.

(2) If the AMS Administrator denies an appeal, the State or Tribal hemp production plan will be suspended or revoked as applicable. Producers located in that State or territory of the Indian Tribe may continue to produce hemp under their State or Tribal license until the end the calendar year in which the State or Tribal plan's disapproval was effective or when the State or Tribal license expires, whichever is earlier. Producers may apply for a USDA license under subpart C of this part unless hemp production is otherwise prohibited by the State or Indian Tribe. The State or Indian Tribe may request a formal adjudicatory proceeding be initiated to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(c) *Filing period.* The appeal of a State or Tribal hemp production plan suspension or revocation must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the AMS Administrator. The decision to deny a

State or Tribal plan application or suspend or revoke approval of a plan, is final unless the decision is appealed in a timely manner.

(d) *Where to file.* Appeals to the Administrator must be filed in the manner as determined by AMS.

(e) *What to include in appeal.* All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations in this part, policies, or procedures.

Subpart E—Administrative Provisions

§ 990.60 Agents.

As provided under 7 CFR part 2, the Secretary may name any officer or employee of the United States or name any agency or division in the United States Department of Agriculture, to act as their agent or representative in connection with any of the provisions of this part.

§ 990.61 Severability.

If any provision of this part is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this part or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 990.62 Expiration of this part.

This part expires on [INSERT DATE 730 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] unless extended by notification in the Federal Register. State and Tribal plans approved under subpart B of this part remain in effect after [INSERT DATE 730 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] unless USDA

disapproves the plan. USDA hemp producer licenses issued under subpart C of this part remain in effect until they expire unless USDA revokes or suspends the license.

§ 990.63 Interstate transportation of hemp.

No State or Indian Tribe may prohibit the transportation or shipment of hemp or hemp products lawfully produced under a State or Tribal plan approved under subpart B of this part, under a license issued under subpart C of this part, or under 7 U.S.C. 5940 through the State or territory of the Indian Tribe, as applicable.

Subpart F—Reporting Requirements

§ 990.70 State and Tribal hemp reporting requirements.

(a) *State and Tribal hemp producer report.* Each State and Tribes with a plan approved under this part shall submit to USDA, by the first of each month, a report providing the contact information and the status of the license or other authorization issued for each producer covered under the individual State and Tribal plans. If the first of the month falls on a weekend or holiday, the report is due by the first business day following the due date. The report shall be submitted using a digital format compatible with USDA’s information sharing systems, whenever possible. The report shall contain the information described in this paragraph (a).

(1)(i) For each new producer who is an individual and is licensed or authorized under the State or Tribal plan, the report shall include full name of the individual, license or authorization identifier, business address, telephone number, and email address (if available).

(ii) For each new producer that is an entity and is licensed or authorized under the State or Tribal plan, the report shall include full name of the entity, the principal business location

address, license or authorization identifier, and the full name, title, and email address (if available) of each employee for whom the entity is required to submit a criminal history record report.

(iii) For each producer that was included in a previous report and whose reported information has changed, the report shall include the previously reported information and the new information.

(2) The status of each producer's license or authorization.

(3) The period covered by the report.

(4) Indication that there were no changes during the current reporting cycle, if applicable.

(b) *State and Tribal hemp disposal report.* If a producer has produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of in accordance with the Controlled Substances Act and DEA regulations found at 21 CFR 1317.15. States and Tribes with plans approved under this part shall submit to USDA, by the first of each month, a report notifying USDA of any occurrence of non-conforming plants or plant material and providing a disposal record of those plants and materials. This report would include information regarding name and contact information for each producer subject to a disposal during the reporting period, and date disposal was completed. If the first of the month fall on a weekend or holiday, reports are due by the first business day following the due date. The report shall contain the information described in this paragraph (b).

(1) Name and address of the producer.

(2) Producer license or authorization identifier.

(3) Location information, such as lot number, location type, and geospatial location or other location descriptor for the production area subject to disposal.

(4) Information on the agent handling the disposal.

(5) Disposal completion date.

(6) Total acreage.

(c) *Annual report.* Each State or Tribe with a plan approved under this part shall submit an annual report to USDA. The report form shall be submitted by December 15 of each year and contain the information described in this paragraph (c).

(1) Total planted acreage.

(2) Total harvested acreage.

(3) Total acreage disposed.

(d) *Test results report.* Each producer must ensure that the DEA-registered laboratory that conducts the test of the sample(s) from its lots reports the test results for all samples tested to USDA. The test results report shall contain the information described in this paragraph (d) for each sample tested.

(1) Producer's license or authorization identifier.

(2) Name of producer.

(3) Business address of producer.

(4) Lot identification number for the sample.

(5) Name and DEA registration number of laboratory.

(6) Date of test and report.

(7) Identification of a retest.

(8) Test result.

§ 990.71 USDA plan reporting requirements.

(a) *USDA hemp plan producer licensing application.* USDA will accept applications from [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] through November 2, 2020. Thereafter applicants, may submit a USDA Hemp Licensing Application to USDA from August 1 through October 31 of each year. Licenses will be valid until December 31 of the year three years after the license is issued. The license application will be used for both new applicants and for producers seeking renewal of their license. The application shall include the information described in this paragraph (a).

(1) *Contact information.* (i) For an applicant who is an individual, the application shall include full name of the individual, business address, telephone number, and email address (if available).

(ii) For an applicant that is an entity, the application shall include full name of the entity, the principal business location address, and the full name, title, and email address (if available) of each key participant of the entity.

(2) *Criminal history report.* As part of a complete application, each applicant shall provide a current Federal Bureau of Investigation's Identity History Summary. If the applicant is a business entity, a criminal history report shall be provided for each key participant.

(i) The applicant shall ensure the criminal history report accompanies the application.

(ii) The criminal history report must be dated within 60 days of submission of the application submittal.

(3) *Consent to comply with program requirements.* All applicants submitting a completed

license application, in doing so, consent to comply with the requirements of this part.

(b) *USDA hemp plan producer disposal form.* If a producer has produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of in accordance with the Controlled Substances Act and DEA regulations found at 21 CFR 1317.15. Forms shall be submitted to USDA no later than 30 days after the date of completion of disposal. The report shall contain the information described in this paragraph (b).

(1) Name and address of the producer.

(2) Producer's license number.

(3) Geospatial location, or other valid land descriptor, for the production area subject to disposal.

(4) Information on the agent handling the disposal.

(5) Date of completion of disposal.

(6) Signature of the producer.

(7) Disposal agent certification of the completion of the disposal.

(c) *USDA hemp plan producer annual report.* Each producer shall submit an annual report to USDA. The report form shall be submitted by December 15 of each year and contain the information described in this paragraph (c).

(1) Producer's license number.

(2) Producer's name.

(3) Producer's address.

(4) Lot, location type, geospatial location, total planted acreage, total acreage disposed, and total harvested acreage.

(d) *Test results report.* Each producer must ensure that the DEA-registered laboratory that conducts the test of the sample(s) from its lots reports the test results for all samples tested to USDA. The test results report shall contain the information described in this paragraph (d) for each sample tested.

- (1) Producer's license number.
- (2) Name of producer.
- (3) Business address of producer.
- (4) Lot identification number for the sample.
- (5) Name and DEA registration number of laboratory.
- (6) Date of test and report.
- (7) Identification of a retest.
- (8) Test result.

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Bruce Summers,

Administrator,

Agricultural Marketing Service.

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